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(54) **Open vessel sealing instrument with hourglass cutting mechanism and over-ratchet safety**

(57) An open electrosurgical forceps for sealing tissue includes a pair of first and second shaft members each having a jaw member disposed at a distal end thereof. The jaw members are movable from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween. Each of the jaw members includes an electrically conductive sealing plate for communicating electrosurgical energy through tissue held therebetween. At least one of the jaw members includes a knife channel defined along a length thereof

which is dimensioned to reciprocate a cutting blade therealong. An actuator is included which is operatively connected to one of the shaft members and selectively advances the cutting mechanism from a first position wherein the cutting blade is disposed proximal to tissue held between the jaw members to at least one subsequent position wherein the cutting blade is disposed distal to tissue held between the jaw members. The cutting blade is a generally hourglass-shaped flexible cutting blade having a notch disposed generally midway therealong which facilitates distal translation of the knife within the knife channel.

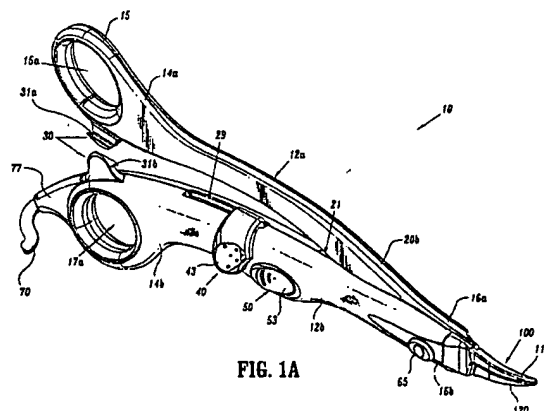
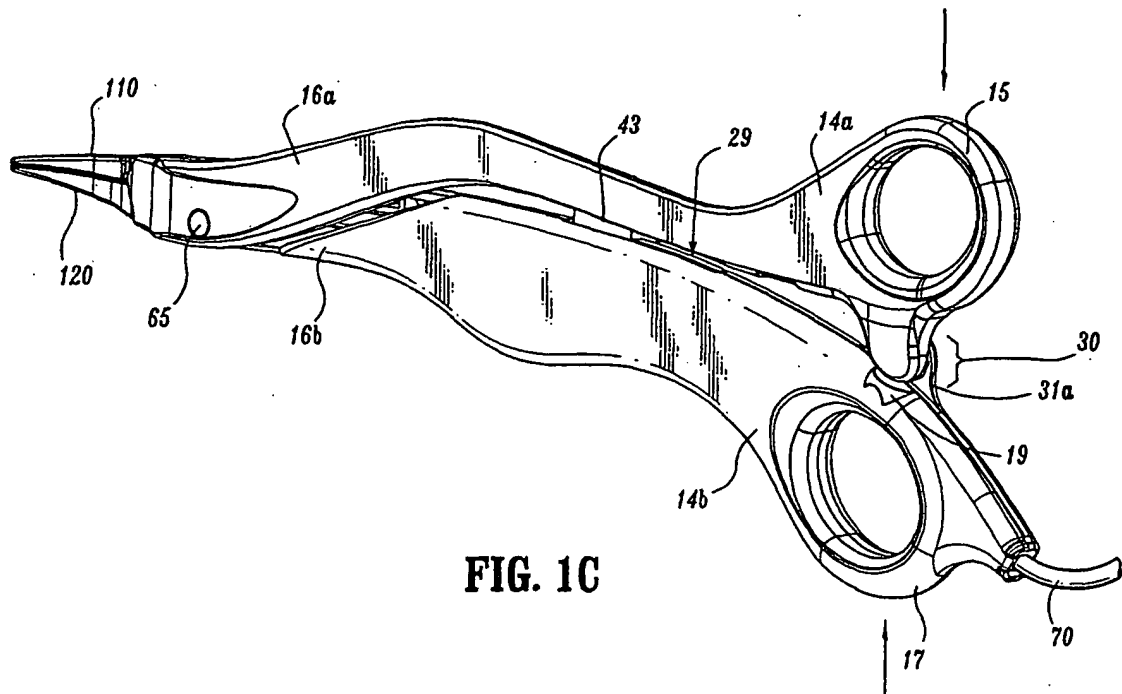
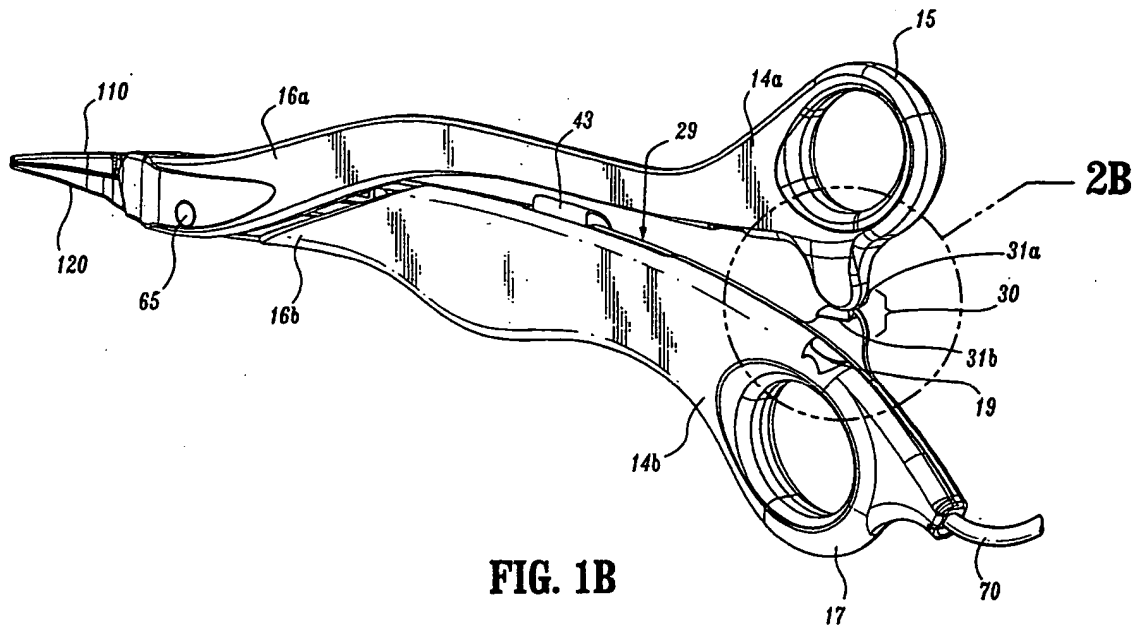


FIG. 1A

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Description

BACKGROUND

[0001] The present disclosure relates to forceps used for open surgical procedures. More particularly, the present disclosure relates to an open forceps which applies a combination of mechanical clamping pressure and electrosurgical energy to seal tissue and a knife which is selectively advanceable to sever tissue along the tissue seal.

Technical Field

[0002] A forceps is a plier-like instrument which relies on mechanical action between its jaws to grasp, clamp and constrict vessels or tissue. So-called "open forceps" are commonly used in open surgical procedures whereas "endoscopic forceps" or "laparoscopic forceps" are, as the name implies, used for less invasive endoscopic surgical procedures. Electrosurgical forceps (open or endoscopic) utilize both mechanical clamping action and electrical energy to effect hemostasis by heating tissue and blood vessels to coagulate and/or cauterize tissue.

[0003] Certain surgical procedures require more than simply cauterizing tissue and rely on the unique combination of clamping pressure, precise electrosurgical energy control and gap distance (i.e., distance between opposing jaw members when closed about tissue) to "seal" tissue, vessels and certain vascular bundles.

[0004] Vessel sealing or tissue sealing is a recently-developed technology which utilizes a unique combination of radiofrequency energy, pressure and gap control to effectively seal or fuse tissue between two opposing jaw members or sealing plates. Vessel or tissue sealing is more than "cauterization" which involves the use of heat to destroy tissue (also called "diathermy" or "electrodiathermy"). Vessel sealing is also more than "coagulation" which is the process of desiccating tissue wherein the tissue cells are ruptured and dried. "Vessel sealing" is defined as the process of liquefying the collagen, elastin and ground substances in the tissue so that the tissue reforms into a fused mass with significantly-reduced demarcation between the opposing tissue structures.

[0005] In order to effectively "seal" tissue or vessels, two predominant mechanical parameters must be accurately controlled: 1) the pressure or closure force applied to the vessel or tissue; and 2) the gap distance between the conductive tissue contacting surfaces (electrodes). As can be appreciated, both of these parameters are affected by the thickness of the tissue being sealed. Accurate application of pressure is important for several reasons: to reduce the tissue impedance to a low enough value that allows enough electrosurgical energy through the tissue; to overcome the forces of expansion during tissue heating; and to contribute to the end tissue thickness which is an indication of a good seal. It has been determined that a good seal for certain tissues is optimum

between about 0.001 inches and about 0.006 inches.

[0006] With respect to smaller vessels or tissue, the pressure applied becomes less relevant and the gap distance between the electrically conductive surfaces becomes more significant for effective sealing. In other words, the chances of the two electrically conductive surfaces touching during activation increases as the tissue thickness and the vessels become smaller.

[0007] Commonly owned, U.S. Patent No. 6,511,480, PCT Patent Application Nos. PCT/US01/11420 and PCT/US01/11218, U.S. Patent Applications Serial Nos. 10/116,824, 10/284,562 and 10/299,650 all describe various open surgical forceps which seal tissue and vessels. All of these references are hereby incorporated by reference herein. In addition, several journal articles have disclosed methods for sealing small blood vessels using electrosurgery. An article entitled Studies on Coagulation and the Development of an Automatic Computerized Bipolar Coagulator, J. Neurosurg., Volume 75, July 1991, describes a bipolar coagulator which is used to seal small blood vessels. The article states that it is not possible to safely coagulate arteries with a diameter larger than 2 to 2.5 mm. A second article is entitled Automatically Controlled Bipolar Electrocoagulation - "COA-COMP", Neurosurg. Rev. (1984), pp. 187-190, describes a method for terminating electrosurgical power to the vessel so that charring of the vessel walls can be avoided.

[0008] Typically and particularly with respect to open electrosurgical procedures, once a vessel is sealed, the surgeon has to remove the sealing instrument from the operative site, substitute a new instrument and accurately sever the vessel along the newly formed tissue seal. As can be appreciated, this additional step may be both time consuming (particularly when sealing a significant number of vessels) and may contribute to imprecise separation of the tissue along the sealing line due to the misalignment or misplacement of the severing instrument along the center of the tissue sealing line.

[0009] Many endoscopic vessel sealing instruments have been designed which incorporate a knife or blade member which effectively severs the tissue after forming a tissue seal. For example, commonly-owned U.S. Application Serial Nos. 10/116,944 and 10/179,863 describe one such endoscopic instrument which effectively seals and cuts tissue along the tissue seal. Other instruments include blade members or shearing members which simply cut tissue in a mechanical and/or electro-mechanical manner and are relatively ineffective for vessel sealing purposes.

[0010] There exists a need to develop an open electrosurgical forceps which is simple, reliable and inexpensive to manufacture and which effectively seals tissue and vessels and which allows a surgeon to utilize the same instrument to effectively sever the tissue along the newly formed tissue seal.

SUMMARY

[0011] The present disclosure relates to an open electrosurgical forceps for sealing tissue and includes a pair of first and second shaft members each having a jaw member disposed at a distal end thereof. The jaw members are movable from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween. Each jaw member includes an electrically conductive sealing plate for communicating electrosurgical energy through tissue held therebetween upon activation of the forceps. At least one of the jaw members includes a knife channel defined along a length thereof which is dimensioned to reciprocate a cutting mechanism therealong.

[0012] Preferably, an actuator is included which is operatively connected to one of the shaft members and is configured to selectively advance the cutting mechanism from a first position wherein the cutting mechanism is distally translated through tissue held between the jaw members. The cutting mechanism includes a generally hourglass-shaped flexible knife blade having a notch disposed generally midway therealong which facilitates distal translation of the knife within the knife channel.

[0013] In one embodiment, the actuator includes a rack and pinion system having a first gear-like rack connected to the trigger; a second gear-like rack connected to the cutting mechanism; and a pinion disposed between the first and second racks. A safety lockout may also be included which is designed to prevent reciprocation of the cutting mechanism when the jaw members are disposed in the first position. The safety lockout may be dimensioned as part of one of the jaw members and/or part of the cutting mechanism.

[0014] Another embodiment according to the present invention includes an open electrosurgical forceps for sealing tissue having a pair of first and second shaft members each including a jaw member disposed at a distal end thereof. The jaw members are movable from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween. Preferably, each of the jaw members includes an electrically conductive sealing plate attached thereto for selectively communicating electrosurgical energy through tissue held therebetween to effect a tissue seal. A ratchet is included having first and second ratchet interfaces disposed on the first and second shaft members, respectively. The ratchet is configured to maintain a pressure between jaw members within the range of about 3 kg/cm² to about 16 kg/cm². The ratchet preferably includes a stop disposed on one of the shaft members to prevent over pressurizing of the jaw members beyond the first and second ratchet interfaces.

[0015] Preferably, the forceps further includes a knife channel defined along a length of at least one of the jaw members. The knife channel is dimensioned to reciprocate

a cutting mechanism therealong. An actuator is preferably included which is operatively connected to one of the shaft members and selectively advances the cutting mechanism from a first position wherein the cutting mechanism is disposed proximal to tissue held between the jaw members to at least one subsequent position wherein the cutting mechanism is disposed distal to tissue held between the jaw members.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Various embodiments of the subject instrument are described herein with reference to the drawings wherein:

Fig. 1A is a left, front perspective view of an open forceps with a cutting mechanism according to the present disclosure;

Fig. 1B is a right, rear perspective view of the forceps of Fig. 1A shown in open configuration;

Fig. 1C is a right, rear perspective view of the forceps of Fig. 1A shown in closed configuration;

Fig. 2A is a left, side view of the forceps of Fig. 1A;

Fig. 2B is an enlarged view of the area of detail of Fig. 1B;

Fig. 2C is a rear view of the forceps shown in Fig. 1C;

Fig. 3 is an internal, perspective view of the forceps of Fig. 1A showing a rack and pinion actuating mechanism for advancing the cutting mechanism and a series of internally disposed electrical connections for energizing the forceps;

Fig. 4 is an internal, side view of the forceps showing the rack and pinion actuating mechanism and the internally disposed electrical connections;

Fig. 5 is an enlarged, perspective view showing the area of detail in Fig. 3;

Fig. 6 is an enlarged, perspective view showing the area of detail in Fig. 3;

Fig. 7A is a perspective view of the forceps of Fig. 1A with parts separated;

Fig. 7B is an enlarged perspective view of a cutting mechanism of Fig. 7A;

Fig. 7C is an enlarged cross sectional view of an end effector assembly of the forceps of Fig. 1C;

Fig. 8 is a perspective view of one shaft of the forceps

of Fig. 1 A;

Fig. 9 is an enlarged, perspective view showing the area of detail in Fig. 8;

Fig. 10 is an enlarged, perspective view of the cutting mechanism;

Fig. 11 is a side cross section along lines 11-11 of Fig. 10;

Fig. 12 is an enlarged, perspective view of the area of detail in Fig. 10;

Fig. 13 is a greatly-enlarged perspective view of a distal electrical connector of the forceps of Fig. 1A;

Fig. 14 is an enlarged, left perspective view of the one of the jaw members of the forceps of Fig. 1A;

Fig. 15 is an enlarged, right perspective view of the jaw member of Fig. 14;

Fig. 16 is side cross sectional view showing the forceps in open configuration for grasping tissue;

Fig. 17 is a side cross sectional view showing the area of detail in Fig. 16;

Fig. 18 is a rear, perspective view of the forceps of Fig. 1A shown grasping tissue with a ratchet mechanism shown prior to engagement;

Fig. 19 is a rear view of the forceps of Fig. 1A showing the ratchet mechanism engaged;

Fig. 20 is a greatly-enlarged, side cross sectional view showing the forceps in a closed position and defining a gap distance "G" between opposing jaw members;

Fig. 21 is a greatly-enlarged, perspective view of a tissue seal;

Fig. 22 is a side cross sectional view taken along line 22-22 of Fig. 21;

Fig. 23 is a side cross sectional view showing the forceps in a closed position and showing the activation and advancement of the cutting mechanism;

Fig. 24A is an enlarged view of the area of detail in Fig. 23;

Fig. 24B is an enlarged perspective view of the bottom jaw member showing the cutting mechanism in a distally advanced orientation; and

Fig. 25 is a greatly-enlarged, cross sectional view showing tissue separated along the tissue seal after advancement of the cutting mechanism.

5 DETAILED DESCRIPTION

[0017] Referring now to Figs. 1-7A, a forceps 10 for use with open surgical procedures includes elongated shaft portions 12a and 12b each having a proximal end 14a, 14b and a distal end 16a and 16b, respectively. In the drawings and in the descriptions which follow, the term "proximal", as is traditional, will refer to the end of the forceps 10 which is closer to the user, while the term "distal" will refer to the end which is further from the user.

[0018] The forceps 10 includes an end effector assembly 100 which attaches to the distal ends 16a and 16b of shafts 12a and 12b, respectively. As explained in more detail below, the end effector assembly 100 includes pair of opposing jaw members 110 and 120 which are pivotably connected about a pivot pin 65 and which are movable relative to one another to grasp tissue.

[0019] Preferably, each shaft 12a and 12b includes a handle 15 and 17, respectively, disposed at the proximal end 14a and 14b thereof which each define a finger hole 15a and 17a, respectively, therethrough for receiving a finger of the user. As can be appreciated, finger holes 15a and 17a facilitate movement of the shafts 12a and 12b relative to one another which, in turn, pivot the jaw members 110 and 120 from an open position wherein the jaw members 110 and 120 are disposed in spaced relation relative to one another to a clamping or closed position wherein the jaw members 110 and 120 cooperate to grasp tissue therebetween.

[0020] As best seen in Fig. 7A-7C, shaft 12b is constructed from two components, namely, 12b1 and 12b2, which matingly engage one another about the distal end 16a of shaft 12a to form shaft 12b. It is envisioned that the two component halves 12b1 and 12b2 may be ultrasonically-welded together at a plurality of different weld points or the component halves 12b1 and 12b2 may be mechanically engaged in any other known fashion, snap-fit, glued, screwed, etc. After component halves 12b1 and 12b2 are welded together to form shaft 12b, shaft 12a is secured about pivot 65 and positioned within a cut-out or relief 21 defined within shaft portion 12b2 such that shaft 12a is movable relative to shaft 12b. More particularly, when the user moves the shaft 12a relative to shaft 12b to close or open the jaw members 110 and 120, the distal portion of shaft 12a moves within cutout 21 formed within portion 12b2. It is envisioned that configuring the two shafts 12a and 12b in the fashion facilitates gripping and reduces the overall size of the forceps 10 which is especially advantageous during surgeries in small cavities.

[0021] As best illustrated in Fig. 1A-1C, one of the shafts, e.g., 12b, includes a proximal shaft connector 77 which is designed to connect the forceps 10 to a source of electrosurgical energy such as an electrosurgical gen-

erator (not shown). The proximal shaft connector 77 electromechanically engages an electrosurgical cable 70 such that the user may selectively apply electrosurgical energy as needed. Alternatively, the cable 70 may be feed directly into shaft 12b (or 12a).

[0022] As explained in more detail below, the distal end of the cable 70 connects to a handswitch 50 to permit the user to selectively apply electrosurgical energy as needed to seal tissue grasped between jaw members 110 and 120. More particularly, the interior of cable 70 houses leads 71 a, 71b and 71 c which upon activation of the handswitch 50 conduct the different electrical potentials from the electrosurgical generator to the jaw members 110 and 120 (See Figs. 3 and 4). As can be appreciated, positioning the switch 50 on the forceps 10 gives the user more visual and tactile control over the application of electrosurgical energy. These aspects are explained below with respect to the discussion of the handswitch 50 and the electrical connections associated therewith.

[0023] The two opposing jaw members 110 and 120 of the end effector assembly 100 are pivotable about pin 65 from the open position to the closed position for grasping tissue therebetween. Preferably, pivot pin 65 consists of two component halves 65a and 65b which matingly engage and pivotably secure the shafts 12a and 12b during assembly such that the jaw members 110 and 120 are freely pivotable between the open and closed positions. For example, the pivot pin 65 may be configured to be spring loaded such that the pivot snap fits together at assembly to secure the two shafts 12a and 12b for rotation about the pivot pin 65.

[0024] The tissue grasping portions of the jaw members 110 and 120 are generally symmetrical and include similar component features which cooperate to permit facile rotation about pivot pin 65 to effect the grasping and sealing of tissue. As a result and unless otherwise noted, jaw member 110 and the operative features associated therewith are initially described herein in detail and the similar component features with respect to jaw member 120 will be briefly summarized thereafter. Moreover, many of the features of the jaw members 110 and 120 are described in detail in commonly-owned U.S. Patent Application Serial Nos. 10/284,562, 10/116,824, 09/425,696, 09/178,027 and PCT Application Serial No. PCT/US01/11420 the contents of which are all hereby incorporated by reference in their entirety herein.

[0025] As best shown in Figs. 14 and 15, jaw member 110 includes an insulated outer housing 116 which is dimensioned to mechanically engage an electrically conductive sealing surface 112. The outer insulative housing 116 extends along the entire length of jaw member 110 to reduce alternate or stray current paths during sealing and/or incidental burning of tissue. The electrically conductive surface 112 conducts electrosurgical energy of a first potential to the tissue upon activation of the handswitch 50. Insulated outer housing 116 is dimensioned to securely engage the electrically conductive sealing sur-

face 112. It is envisioned that this may be accomplished by stamping, by overmolding, by overmolding a stamped electrically conductive sealing plate and/or by overmolding a metal injection molded seal plate. Other methods of affixing the seal surface 112 to the outer housing 116 are described in detail in one or more of the above-identified references. Preferably, the jaw members 110 and 120 are made from a conductive material and powder coated with an insulative coating to reduce stray current concentrations during sealing.

[0026] It is also contemplated that the electrically conductive sealing surface 112 may include an outer peripheral edge which has a radius and the insulated outer housing 116 meets the electrically conductive sealing surface 112 along an adjoining edge which is generally tangential to the radius and/or meets along the radius. Preferably, at the interface, the electrically conductive surface 112 is raised relative to the insulated outer housing 116. Alternatively, the jaw member 110 including the sealing plate 112 and the outer insulative housing 116 may be formed as part of a molding process to facilitate manufacturing and assembly. These and other envisioned embodiments are discussed in commonly-owned, co-pending PCT Application Serial No. PCT/US01/11412 and commonly owned, co-pending PCT Application Serial No. PCT/US01/11411, the contents of both of these applications being incorporated by reference herein in their entirety.

[0027] Preferably, the insulated outer housing 116 and the electrically conductive sealing surface 112 are dimensioned to limit and/or reduce many of the known undesirable effects related to tissue sealing, e.g., flashover, thermal spread and stray current dissipation. All of the aforementioned and cross referenced manufacturing techniques produce an electrode having an electrically conductive surface 112 which is substantially surrounded by an insulated outer housing 116.

[0028] Likewise, jaw member 120 includes similar elements which include: an outer housing 126 which engages an electrically conductive sealing surface 122 and an electrically conductive sealing surface 122 which conducts electrosurgical energy of a second potential to the tissue upon activation of the handswitch 50.

[0029] It is envisioned that one of the jaw members, e.g., 120, includes at least one stop member 175 disposed on the inner facing surface of the electrically conductive sealing surface 122 (and/or 112). Alternatively or in addition, the stop member 175 may be positioned adjacent to the electrically conductive sealing surfaces 112, 122 or proximate the pivot pin 65. The stop member(s) is preferably designed to facilitate gripping and manipulation of tissue and to define a gap "G" between opposing jaw members 110 and 120 during sealing (See Figs. 18 and 20). Preferably the separation distance during sealing or the gap distance "G" is within the range of about 0.001 inches (-0.03 millimeters) to about 0.006 inches (-0.016 millimeters). In one particular preferred embodiment and as best shown on Fig. 9 a stop member 175 is

positioned on either side of the knife channel 115 generally midway along the length of the bottom jaw member 120. In addition or alternatively, another stop member may be positioned at the distal end of the jaw member 120 to control the distance between the sealing surface 112 and 122 when the jaw members close about tissue to effect consistent and effective vessel sealing (See Fig. 24B).

[0030] A detailed discussion of these and other envisioned stop members 175 as well as various manufacturing and assembling processes for attaching, disposing, depositing and/or affixing the stop members to the electrically conductive sealing surfaces 112, 122 are described in commonly-assigned, co-pending PCT Application Serial No. PCT/US01/11222 which is hereby incorporated by reference in its entirety herein.

[0031] As mentioned above, two mechanical factors play an important role in determining the resulting thickness of the sealed tissue and effectiveness of the seal, i.e., the pressure applied between opposing jaw members 110 and 120 and the gap "G" between the opposing jaw members 110 and 120 (or opposing seal surfaces 112 and 122 during activation). It is known that the thickness of the resulting tissue seal cannot be adequately controlled by force alone. In other words, too much force and the sealing surfaces 112 and 122 of the two jaw members 110 and 120 would touch and possibly short resulting in little energy traveling through the tissue thus resulting in a bad seal. Too little force and the seal would be too thick. Applying the correct force is also important for other reasons: to oppose the walls of the vessel; to reduce the tissue impedence to a low enough value that allows enough current through the tissue; and to overcome the forces of expansion during tissue heating in addition to contributing towards creating the required end tissue thickness which is an indication of a good seal.

[0032] Preferably, the seal surfaces 112 and 122 are relatively flat to avoid current concentrations at sharp edges and to avoid arcing between high points. In addition and due to the reaction force of the tissue when engaged, jaw members 110 and 120 are preferably manufactured to resist bending, i.e., tapered along their length which provides a constant pressure for a constant tissue thickness at parallel and the thicker proximal portion of the jaw members 110 and 120 will resist bending due to the reaction force of the tissue.

[0033] As best seen in Figs. 9 and 14, the jaw members 110 and 120 include a knife channel 115 disposed therebetween which is configured to allow reciprocation of a cutting mechanism 80 therewithin. One example of a knife channel is disclosed in commonly-owned U.S. Patent Application Serial No. 10/284,562 the entire contents of which are hereby incorporated by reference herein. Preferably, the complete knife channel 115 is formed when two opposing channel halves 115a and 115b associated with respective jaw members 110 and 120 come together upon grasping of the tissue. It is envisioned that the knife channel 115 may be tapered or some other con-

figuration which facilitates or enhances cutting of the tissue during reciprocation of the cutting mechanism 80 in the distal direction. Moreover, the knife channel 115 may be formed with one or more safety features which prevent the cutting mechanism 80 from advancing through the tissue until the jaw members 110 and 120 are closed about the tissue.

[0034] The arrangement of shaft 12b is slightly different from shaft 12a. More particularly, shaft 12b is generally hollow to define a chamber 28 therethrough which is dimensioned to house the handswitch 50 (and the electrical components associated therewith), the actuating mechanism 40 and the cutting mechanism 80. As best seen in Figs. 3, 4 and 7A, the actuating mechanism 40 includes a rack and pinion system having first and second gear tracks 42 and 86, respectively, and a pinion 45 to advance the cutting mechanism 80. More particularly, the actuating mechanism 40 includes a trigger or finger tab 43 which is operatively associated with a first gear rack 42 such that movement of the trigger or finger tab 43 moves the first rack 42 in a corresponding direction. The actuating mechanism 40 mechanically cooperates with a second gear rack 86 which is operatively associated with a drive rod 89 and which advances the entire cutting mechanism 80 as will be explained in more detail below. Drive rod 89 includes a distal end 81 which is configured to mechanically support the cutting blade 87 and which acts as part of a safety lockout mechanism as explained in more detail below.

[0035] Interdisposed between the first and second gear racks 42 and 86, respectively, is a pinion gear 45 which mechanically meshes with both gear racks 42 and 86 and converts proximal motion of the trigger 43 into distal translation of the drive rod 89 and vice versa. More particularly, when the user pulls the trigger 43 in a proximal direction within a predisposed channel 29 in the shaft 12b (See arrow "A" in Fig. 23), the first rack 42 is translated proximally which, in turn, rotates the pinion gear 45 in a counter-clockwise direction. Rotation of the pinion gear 45 in a counter-clockwise direction forces the second rack 86 to translate the drive rod 89 distally (See arrow "B" in Fig. 23) which advances the blade 87 of the cutting mechanism 80 through tissue 400 grasped between jaw members 110 and 120, i.e., the cutting mechanism 80, e.g., knife, blade, wire, etc., is advanced through channel 115 upon distal translation of the drive rod 89.

[0036] It is envisioned that multiple gears or gears with different gear ratios may be employed to reduce surgical fatigue which may be associated with advancing the cutting mechanism 80. In addition, it is contemplated the gear tracks 42 and 86 are configured to include a plurality of gear teeth tracks 43 and 87, respectively, which may be of different length to provide additional mechanical advantage for advancing the jaw members 110 and 120 through tissue. The rack and pinion arrangement may be curved for spatial purposes and to facilitate handling and/or to enhance the overall ergonomics of the forceps

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[0037] A spring 83 may be employed within chamber 28 to bias the first rack 42 upon proximal movement thereof such that upon release of the trigger 43, the force of the spring 83 automatically returns the first rack 42 to its distal most position within channel 29. Obviously, spring 83 may be operatively connected to bias the second rack 86 to achieve the same purpose.

[0038] Preferably, the trigger 43 includes one or more ergonomically friendly features which enhance the tactile feel and grip for the user to facilitate actuation of the finger tab 43. Such features may include, raised protuberances, rubber inserts, scallops and gripping surfaces and the like. In addition, the downward orientation of the trigger 43 is believed to be particularly advantageous since this orientation tends to minimize accidental or inadvertent activation of the trigger 43 during handling. Moreover, it is contemplated that integrally associating (molding or otherwise forming) the trigger 43 and the gear rack 42 during the manufacturing process minimizes the number of parts which, in turn, simplifies the overall assembly process.

[0039] As best seen in Figs. 5, 9, 10, 11, 12, 17, 20 and 23, a safety lockout mechanism 200 is associated with the actuating assembly 40 and the cutting mechanism 80 to prevent advancement of the cutting mechanism 80 until the jaw members 110 and 120 are positioned and closed about tissue. Other lockout mechanisms and features are described in commonly-owned U.S. Application Serial Nos. 10/460,926, 10/461,550, 10/462,121 and U.S. Provisional Application Serial No. 60/523,387 which are all incorporated by reference herein in their entirety. The safety lockout mechanism includes a series of inter-cooperating elements which work together to prevent unintentional firing of the cutting mechanism 80 when the jaw members 110 and 120 are disposed in the open position.

[0040] More particularly, the distal end 81 of the cutting mechanism 80 is dimensioned to reciprocate within a channel 126b defined in the proximal end of jaw member 120 when jaw member 110 and 120 are disposed in a closed position (see Fig. 9). The proximal end of channel 126b defines a recess or relieved portion 123 therein which includes a forward stop 129 which abuts and prevents advancement of the distal end 81 of the cutting mechanism 80 when the jaw members 110 and 120 are disposed in the open position (See Figs. 9 and 17). The proximal portion of jaw member 120 also includes a guide slot 124 defined therethrough which allows a terminal connector 150 or so called "POGO" pin to ride therein upon movement of the jaw members 110 and 120 from the open to closed positions (See Fig. 17 and 24A). In addition, the proximal end includes an aperture 125 defined therethrough which houses the pivot pin 65. Jaw member 110 also includes a channel 126a which aligns with channel 126b when the jaw members 110 and 120 are disposed in the closed position about tissue.

[0041] As best shown in Figs. 17 and 24A which show

the jaw members 110 and 120 in open and closed orientations, respectively, the operation of the lockout mechanism 200 is easily described. When jaw member 120 is rotated with respect to jaw member 110 about pivot 65 a flanged portion 81a of the distal end 81 of cutting mechanism 80 is slidably incorporated within recess 123 and against stop 129 located in the proximal end of jaw member 120 (See Fig. 12). The stop 129 prevents the cutting mechanism 80 from moving forward due to unintentional actuation of the trigger 43. At the same time, the terminal connector 150 moves freely within slot 124 upon rotation of the jaw members 110 and 120. It is envisioned that the terminal connector 150 is seated within aperture 151 within jaw member 110 and rides within slot 124 of jaw member 120 to provide a "running" or "brush" contact to supply electrosurgical energy to jaw member 120 during the pivoting motion of the forceps 10 (See Fig. 17). Recess 123 also includes a rim or flange 199 which prevents over-rotation of shaft 12a relative to shaft 12b. More particularly and as best seen on Figs. 9 and 17, flange 199 is dimensioned to abut a stop 201 disposed within forceps 110 when rotated to a fully open position to prevent unintentional over-rotation of the forceps 10.

[0042] When the jaw members 110 and 120 are moved to the closed position as illustrated in Fig. 24A, the safety lockout mechanism 200 automatically disengages to allow distal advancement of the cutting mechanism 80. More particularly, when the jaw members 110 and 120 are closed about tissue, the distal end 81 including the flanged portion 81a automatically aligns within the channels 126a and 126 of jaw members 110 and 120, respectively, to allow selective actuation of the cutting mechanism 80. As shown in Fig. 24A, the distal end 81 advances through channel 126a and 126b forcing the knife blade 87 through knife channel 115 (115a and 115b) to cut tissue. As described above, when the actuating flange 43 is released, spring 83 biases the drive rod 89 back to the proximal-most position (not shown) which, in turn, re-aligns distal end 81 with recess 123 to allow the jaw members 110 and 120 to be moved to the open position to release the tissue 400.

[0043] It is envisioned that the safety lockout mechanism 200 may include one or more electrical or electromechanical sensors (not shown) which prevent the cutting mechanism 80 from advancing through tissue until a tissue seal has been created. For example, the safety lockout mechanism 200 could include a sensor which upon completion of a tissue seal activates a switch or release (not shown) which unlocks the cutting mechanism 80 for advancement through tissue.

[0044] As best seen in Figs. 9, 10 and 24B, blade 87 is flexible so it easily advances through the curved knife channel 115. For example, upon distal advancement of the cutting mechanism 80, the cutting blade 87 will simply flex and ride around the knife channel 115 through the tissue 400 held between jaw members 110 and 120. In one particular embodiment and as shown, the blade 87 is flexible and is generally hourglass in configuration and

includes a notched area 87a disposed about midway along the blade 87. The notch 87a reduces the side profile of the blade to facilitate the cutting process. More particularly, the hourglass design of the blade allows the blade 87 to move more easily along the curved knife channel 115 during distal translation thereof. A curved blade (not shown) may also be utilized which has a similar radius of curvature as the knife channel 115 such that the blade will travel through the knife channel 115 without contacting the surfaces of the knife channel 115.

[0045] Figs. 1A, 2A-2C and 19 show a ratchet 30 for selectively locking the jaw members 110 and 120 relative to one another in at least one position during pivoting. A first ratchet interface 31 a extends from the proximal end 14a of shaft member 12a towards a second ratchet interface 31 b on the proximal end 14b of shaft 12b in general vertical registration therewith such that the inner facing surfaces of each ratchet 31 a and 31 b abut one another upon closure of the jaw members 110 and 120 about the tissue 400. It is envisioned that each ratchet interface 31 a and 31 b may include a plurality of step-like flanges (not shown) which project from the inner facing surface of each ratchet interface 31 a and 31 b such that the ratchet interfaces 31 a and 31 b interlock in at least one position. Preferably, each position associated with the cooperating ratchet interfaces 31 a and 31 b holds a specific, i.e., constant, strain energy in the shaft members 12a and 12b which, in turn, transmits a specific closing force to the jaw members 110 and 120.

[0046] It is envisioned that the ratchet 30 may include graduations or other visual markings which enable the user to easily and quickly ascertain and control the amount of closure force desired between the jaw members. It is envisioned that the shafts 12a and 12b may be manufactured from a particular plastic material which is tuned to apply a particular closure pressure within the above-specified working range to the jaw members 110 and 120 when ratcheted. As can be appreciated, this simplified the manufacturing process and eliminates under pressurizing and over pressurizing the jaw members 110 and 120 during the sealing process.

[0047] The proximal connector 77 may include a stop or protrusion 19 (See Figs. 1B, 1C, 2B, 2C and 7A) which prevents the user from over pressurizing the jaw members 110 and 120 by squeezing the handle 15 and 17 beyond the ratchet positions. As can be appreciated this facilitates consistent and effective sealing due to the fact that when ratcheted, the forceps 10 are automatically configured to maintain the necessary closure pressure (about 3 kg/cm² to about 16 kg/cm²) between the opposing jaw members 110 and 120, respectively, to effect sealing. It is known that over pressurizing the jaw members may lead to ineffective tissue sealing.

[0048] It is envisioned that by making the forceps 10 disposable, the forceps 10 is less likely to become damaged since it is only intended for a single use and, therefore, does not require cleaning or re-sterilization. As a result, the functionality and consistency of the vital seal-

ing components, e.g., the conductive surfaces 112 and 122, the stop member(s) 175, and the insulative housings 126 and 116 will assure a uniform and quality seal.

[0049] Figs. 3 and 4 show the electrical details relating to the switch 50. More particularly and as mentioned above, cable 70 includes three electrical leads 71 a, 71 b and 71 c which are fed through shaft 12b. The electro-surgical cable 70 is fed into the bottom of shaft 12b and is held securely therein by one or more mechanical interfaces (not shown). Lead 71c extends directly from cable 70 and connects to jaw member 120 to conduct the second electrical potential thereto. Leads 71 a and 71 b extend from cable 70 and connect to a circuit board 52.

[0050] Several different types of handswitches 50 are envisioned, for example, switch 50 is a regular push-button style switch but may be configured more like a toggle switch which permits the user to selectively activate the forceps 10 in a variety of different orientations, i.e., multi-oriented activation, which simplifies activation. One particular type of handswitch is disclosed in commonly-owned, co-pending U.S. Patent Application Serial No. 10/460,926 the contents of which are hereby incorporated by reference herein.

[0051] The electrical leads 71 a and 71 b are electrically connected to the circuit board 52 such that when the switch 50 is depressed, a trigger lead 72 carries the first electrical potential from the circuit board 52 to jaw member 110. As mentioned above, the second electrical potential is carried by lead 71c directly from the generator (not shown) to jaw member 120 through the terminal connector 150 as described above. It is envisioned that a safety switch or circuit (not shown) may be employed such that the switch 50 cannot fire unless the jaw members 110 and 120 are closed and/or unless the jaw members 110 and 120 have tissue 400 held therebetween. In the latter instance, a sensor (not shown) may be employed to determine if tissue is held therebetween. In addition, other sensor mechanisms may be employed which determine pre-surgical, concurrent surgical (i.e., during surgery) and/or post surgical conditions. The sensor mechanisms may also be utilized with a closed-loop feedback system coupled to the electrosurgical generator to regulate the electrosurgical energy based upon one or more pre-surgical, concurrent surgical or post surgical conditions. Various sensor mechanisms and feedback systems are described in commonly-owned, co-pending U.S. Patent Application Serial No. 10/427,832 the entire contents of which are hereby incorporated by reference herein.

[0052] As best shown in Figs. 1A, 2A and 7A, a switch cap 53 is positioned in electro-mechanical communication with the circuit board 52 along one side of shaft 12b to facilitate activation of switch 50. As can be appreciated, the position of the switch cap 53 enables the user to easily and selectively energize the jaw members 110 and 120 with a single hand. It is envisioned that the switch cap 53 may be hermetically-sealed to avoid damage to the circuit board 52 during wet operating conditions. In addition, it

is contemplated that by positioning the switch cap 53 at a point distal to the actuating assembly 40, the overall sealing process is greatly simplified and ergonomically advantageous to the surgeon, i.e., after activation, the surgeon's finger is automatically poised for actuation of the actuating assembly 40 to advance the cutting mechanism 80. The geometry also disallows inadvertent actuation of the forceps 10 when the forceps 10 is not activated or "powered down".

[0053] The jaw members 110 and 120 are electrically isolated from one another such that electrosurgical energy can be effectively transferred through the tissue to form a tissue seal. Preferably, each jaw member, e.g., 110, includes a uniquely-designed electrosurgical cable path disposed therethrough which transmits electrosurgical energy to the electrically conductive sealing surface 112. It is envisioned that the jaw members 110 and 120 may include one or more cable guides or crimp-like electrical connectors to direct the cable leads towards electrically conductive sealing surfaces 112 and 122. Preferably, cable leads are held securely along the cable path to permit pivoting of the jaw members 110 and 120 about pivot 65.

[0054] As best shown in Fig. 7A, the cable leads 71a, 71b and 71c are protected by two insulative layers, an outer protective sheath which surrounds all three leads 71a, 71b and 71c and a secondary protective sheath which surrounds each individual cable lead, 71a, 71b and 71c, respectively. The two electrical potentials are isolated from one another by virtue of the insulative sheathing surrounding each cable lead 71a, 71b and 71c.

[0055] In operation, the surgeon simply utilizes the two opposing handle members 15 and 17 to grasp tissue between jaw members 110 and 120. The surgeon then activates the handswitch 50 to provide electrosurgical energy to each jaw member 110 and 120 to communicate energy through the tissue held therebetween to effect a tissue seal (See Figs. 21 and 22). Once sealed, the surgeon activates the actuating mechanism 40 to advance the cutting blade 87 through the tissue to sever the tissue 400 along the tissue seal (See Fig. 25).

[0056] From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the same. For example, although the electrical connections are preferably incorporated within one shaft 12b and the forceps 10 is intended for right-handed use, it is contemplated the electrical connections may be incorporated within the other shaft 12a depending upon a particular purpose and/or to facilitate manipulation by a left-handed user. Alternatively, the forceps 10 may operated in an upside down orientation for left-handed users without compromising or restricting any operating characteristics of the forceps 10.

[0057] It is also contemplated that the forceps 10 (and/or the electrosurgical generator used in connection

with the forceps 10) may include a sensor or feedback mechanism (not shown) which automatically selects the appropriate amount of electrosurgical energy to effectively seal the particularly-sized tissue grasped between the jaw members 110 and 120. The sensor or feedback mechanism may also measure the impedance across the tissue during sealing and provide an indicator (visual and/or audible) that an effective seal has been created between the jaw members 110 and 120. Commonly-owned U.S. Patent Application Serial No. 10/427,832 discloses several different types of sensory feedback mechanisms and algorithms which may be utilized for this purpose. The contents of this application are hereby incorporated by reference herein.

[0058] Experimental results suggest that the magnitude of pressure exerted on the tissue by the sealing surfaces of the jaw members 110 and 120 is important in assuring a proper surgical outcome. Tissue pressures within a working range of about 3 kg/cm² to about 16 kg/cm² and, preferably, within a working range of 7 kg/cm² to 13 kg/cm² have been shown to be effective for sealing arteries and vascular bundles. Tissue pressures within the range of about 4 kg/cm² to about 10 kg/cm² have proven to be particularly effective in sealing arteries and tissue bundles. Preferably, the inter-engaging surfaces 31a and 31b of the ratchet 30 are positioned to provide a closure within this working range. In addition and if the ratchet 30 includes multiple positions as explained above, it is envisioned that each particular ratchet position employs a specific closure force on tissue for particular surgical purposes. For example, the shafts 12a and 12b may be manufactured such that the spring constants of the shaft portions 12a and 12b, in conjunction with the placement of the ratchet interfaces 31a and 31b, will yield pressures within the above working range. If desired, the forceps 10 may be manufactured to include successive ratchet positions, i.e., ratchet interfaces 21a and 31b which would increase the closure force between opposing sealing surfaces 112 and 122 incrementally within the above working range or, if desired, outside the working range to suit a particular surgical purpose.

[0059] It is also envisioned that the drive rod 89 may be connected to the same or alternate source of electrosurgical energy and may be selectively energizable by the surgeon during cutting. As can be appreciated, this would enable the surgeon to electrosurgically cut the tissue along the tissue seal. As a result thereof, a substantially dull blade may be employed to electrosurgically cut the tissue. It is also envisioned that a substantially dull blade may be utilized with a spring loaded non-electrically energized cutting mechanism which, due to the clamping pressure between the opposing jaw members 110 and 120 and due to the force at which the spring-loaded cutting mechanism advances the blade, the tissue will sever along the tissue seal.

[0060] It is also contemplated that the forceps may include a safety blade return mechanism (not shown). For example and as mentioned above, the cutting blade 80

may include one or more springs which automatically return the cutting blade 87 after actuation of the actuator 40. In addition, a manual return may be included which allows the user to manually return the blade 87 if the automatic blade return (e.g., spring) should fail due to sticking, skewing, or some other unforeseen surgical condition. Alternatively, the actuating mechanism 40 may be spring-loaded and advanced automatically when tab 43 is depressed by the surgeon. After deployment, the surgeon manually retracts the tab 43 to reset the tab 43 and cutting mechanism 80 for subsequent deployment. [0061] While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

Claims

1. An open electrosurgical forceps for sealing tissue, comprising:

a pair of first and second shaft members each having a jaw member disposed at a distal end thereof, the jaw members being movable from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween;

each of the jaw members including an electrically conductive sealing plate for communicating electrosurgical energy through tissue held therebetween;

at least one of the jaw members including a knife channel defined along a length thereof, the knife channel being dimensioned to reciprocate a cutting mechanism therealong; and

an actuator operatively connected to one of the shaft members for selectively advancing the cutting mechanism from a first position wherein the cutting mechanism is disposed proximal to tissue held between the jaw members to at least one subsequent position wherein the cutting mechanism is disposed distal to tissue held between the jaw members, the cutting mechanism including a generally hourglass-shaped flexible blade having a notch disposed generally midway therealong which facilitates distal translation of the knife within the knife channel.

2. An open electrosurgical forceps for sealing tissue according to claim 1 wherein the actuator includes

a rack and pinion system having:

a first gear-like rack connected to the trigger;

a second gear-like rack connected to the cutting mechanism; and

a pinion disposed between the first and second racks.

3. An open electrosurgical forceps for sealing tissue according to claim 1 further comprising a safety lockout to prevent reciprocation of the cutting mechanism when the jaw members are disposed in the first position.
4. An open electrosurgical forceps for sealing tissue according to claim 3 wherein the safety lockout forms part of at least one of the jaw members.
5. An open electrosurgical forceps for sealing tissue according to claim 3 wherein the safety lockout forms part of the cutting mechanism.
6. An open electrosurgical forceps for sealing tissue, comprising:

a pair of first and second shaft members each having a jaw member disposed at a distal end thereof, the jaw members being movable from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween;

each of the jaw members including an electrically conductive sealing plate for communicating electrosurgical energy through tissue held therebetween to effect a tissue seal; and

a ratchet including first and second ratchet interfaces disposed on the first and second shaft members, respectively, the ratchet configured to maintain a pressure between jaw members within the range of about 3 kg/cm² to about 16 kg/cm², the ratchet including a stop disposed on one of the shaft members to prevent over pressurizing of the jaw members beyond the first and second ratchet interfaces.

7. An open electrosurgical forceps for sealing tissue according to claim 6 further comprising:

a knife channel defined along a length of at least one of the jaw members, the knife channel being dimensioned to reciprocate a cutting mechanism therealong; and

an actuator operatively connected to one of the shaft members for selectively advancing the cutting mechanism from a first position wherein the cutting mechanism is disposed proximal to tissue held between the jaw members to at least

one subsequent position wherein the cutting mechanism is disposed distal to tissue held between the jaw members.

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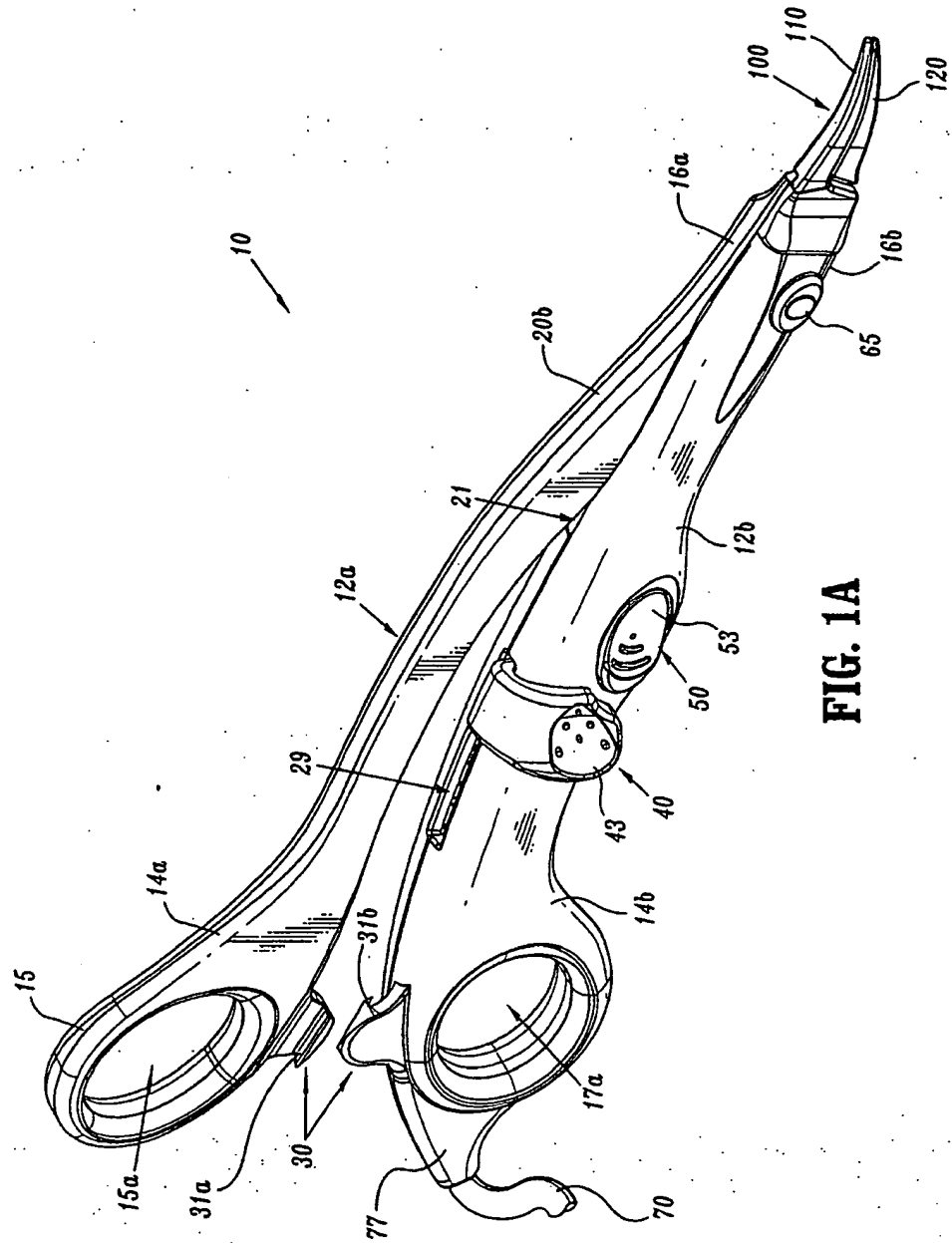


FIG. 1A

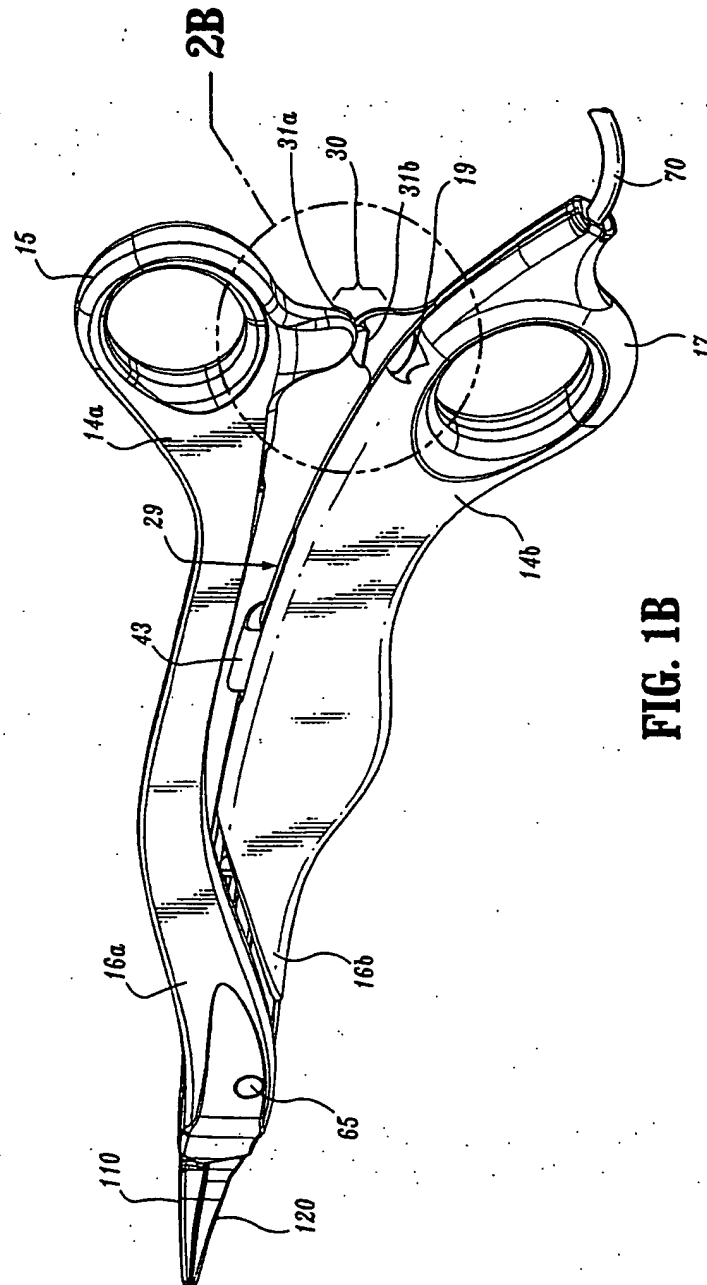


FIG. 1B

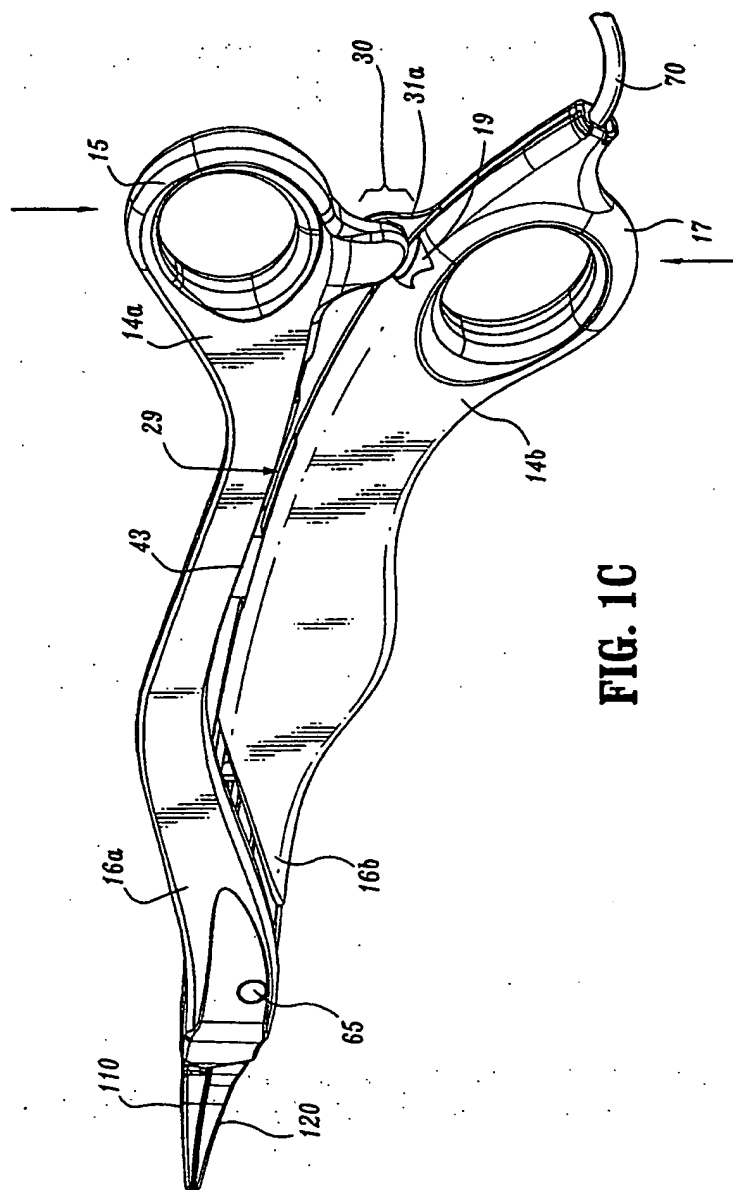


FIG. 1C

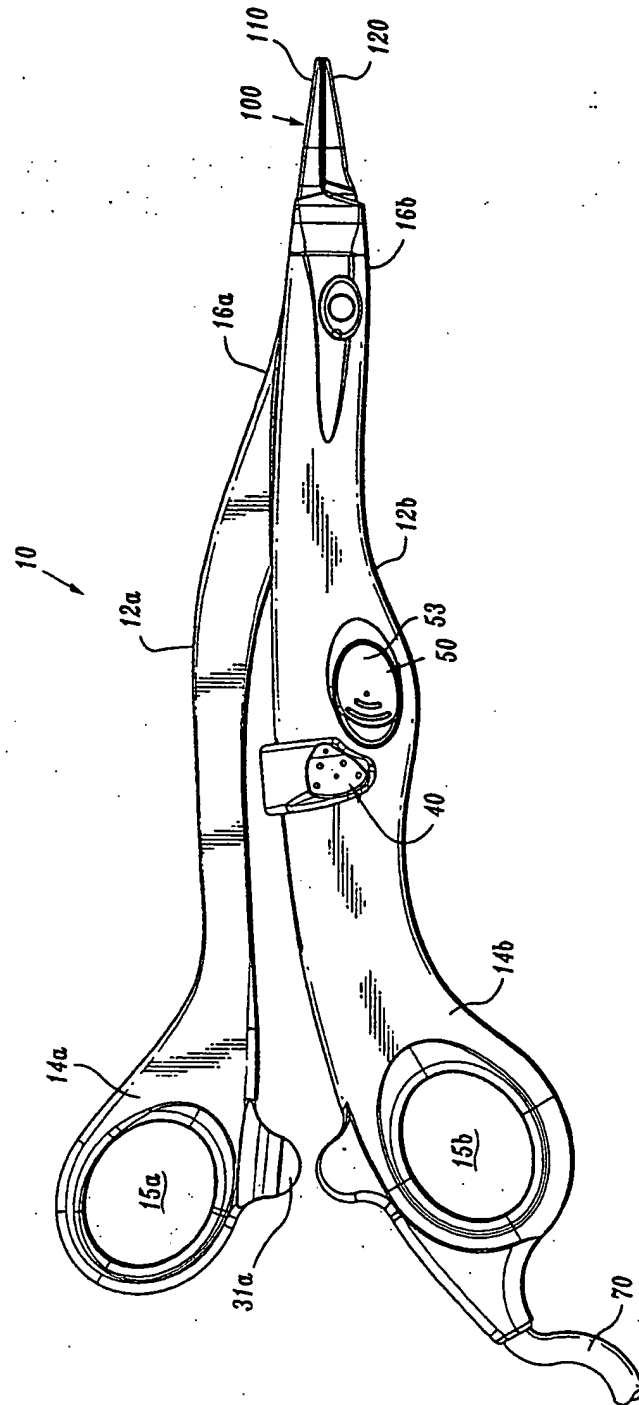


FIG. 2A

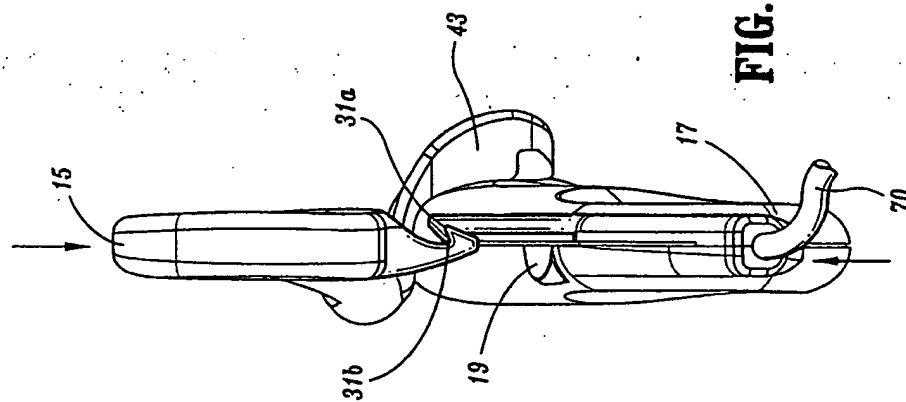


FIG. 2C

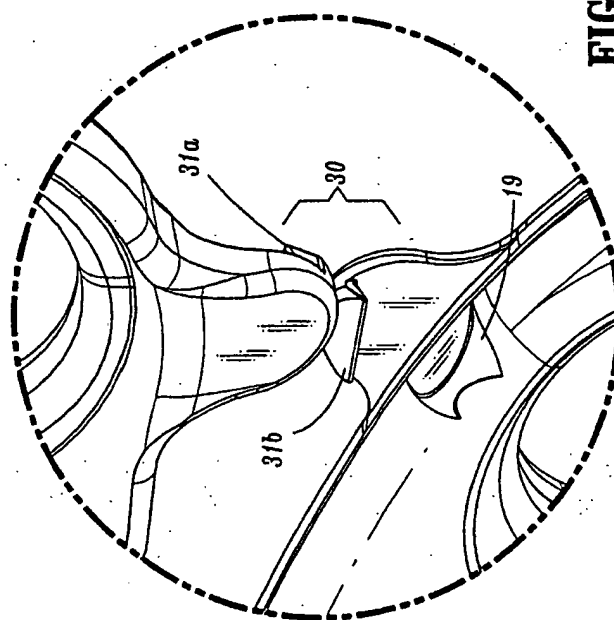


FIG. 2B

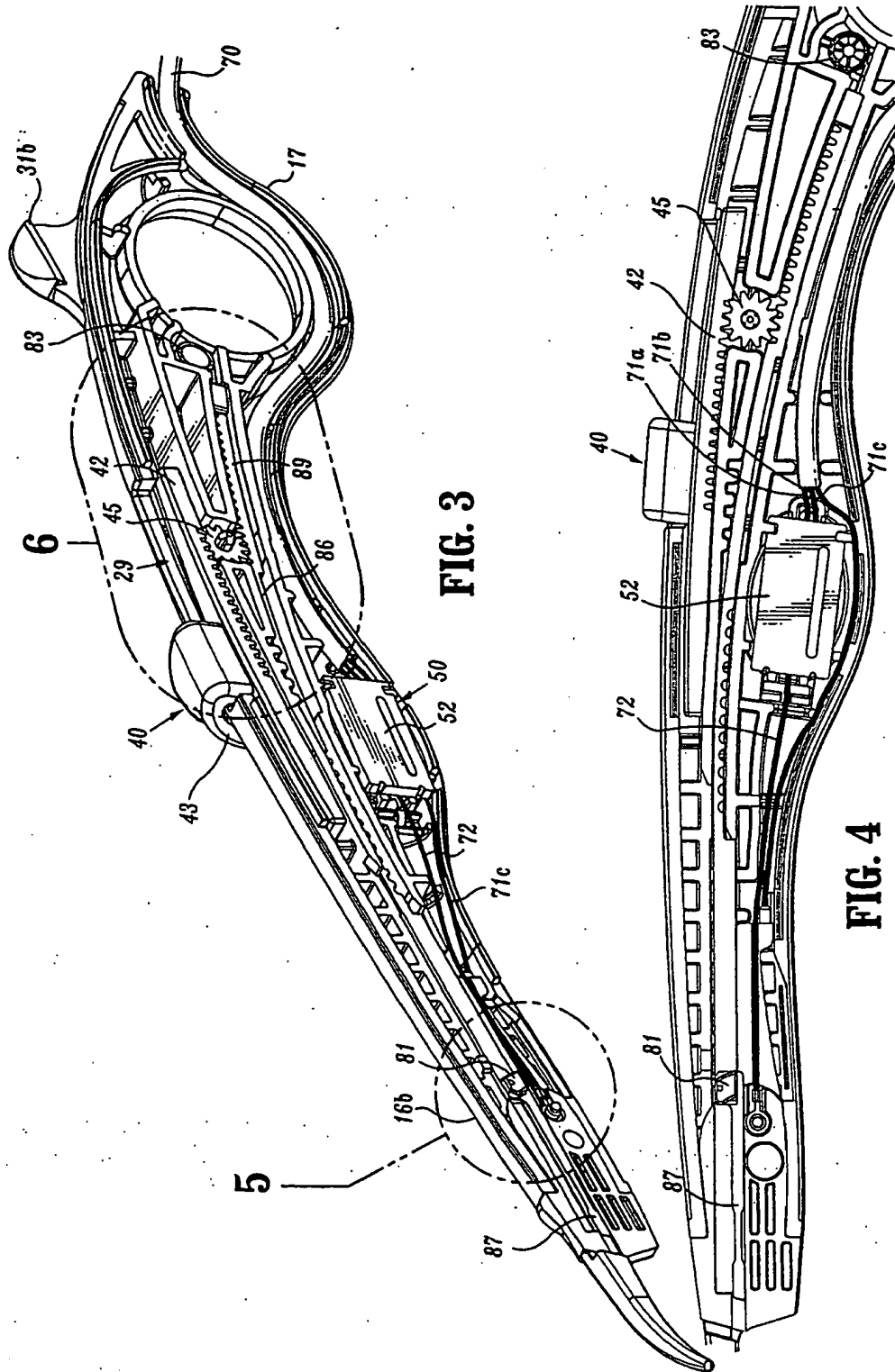


FIG. 3

FIG. 4

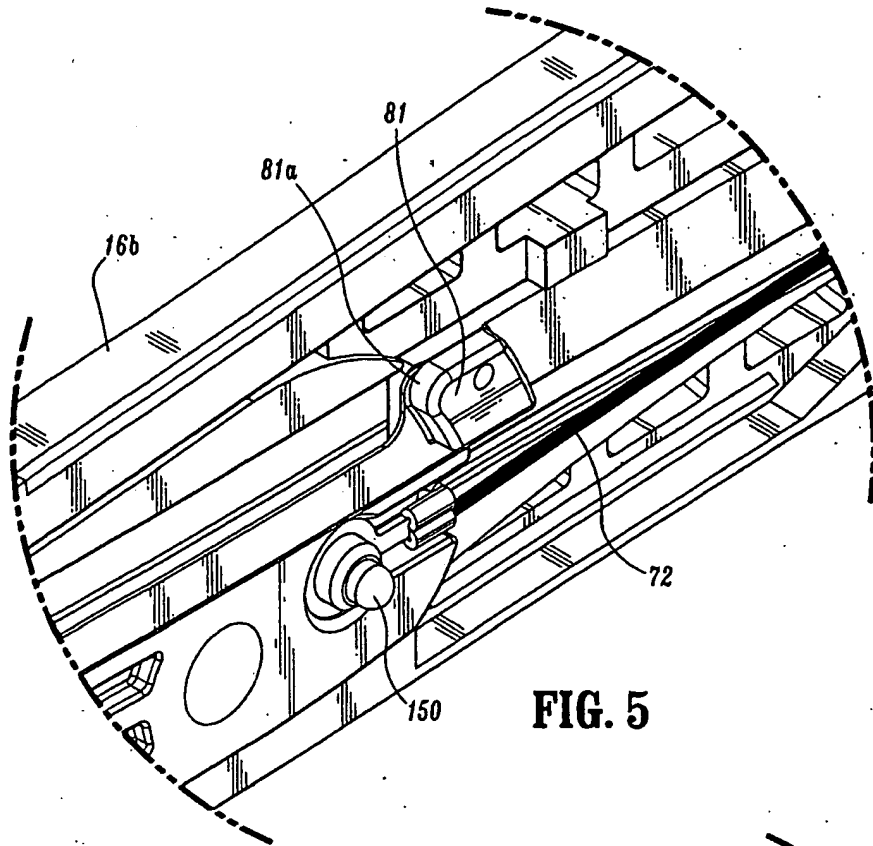


FIG. 5

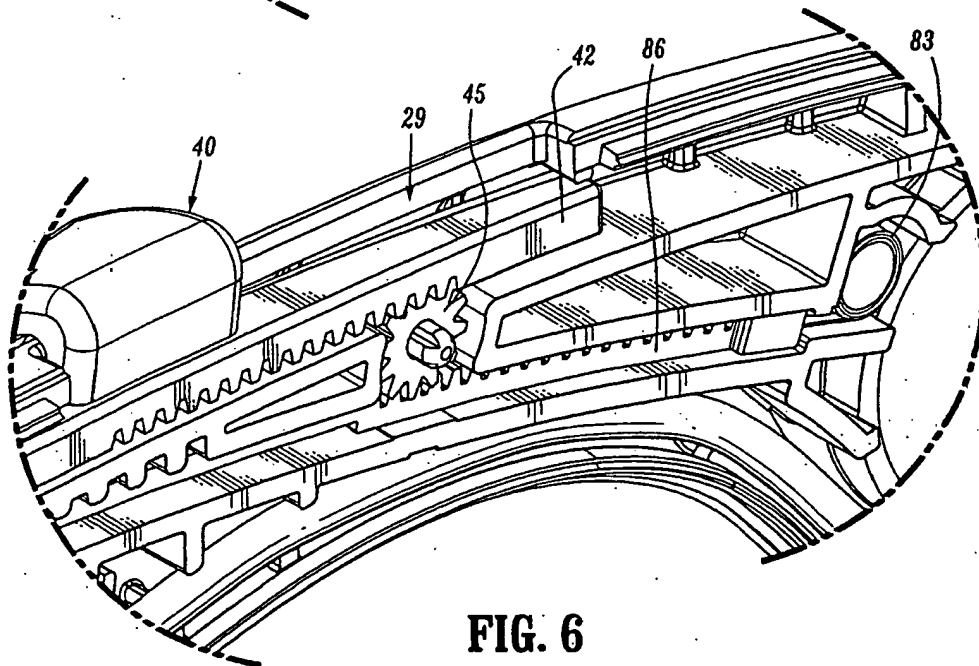


FIG. 6

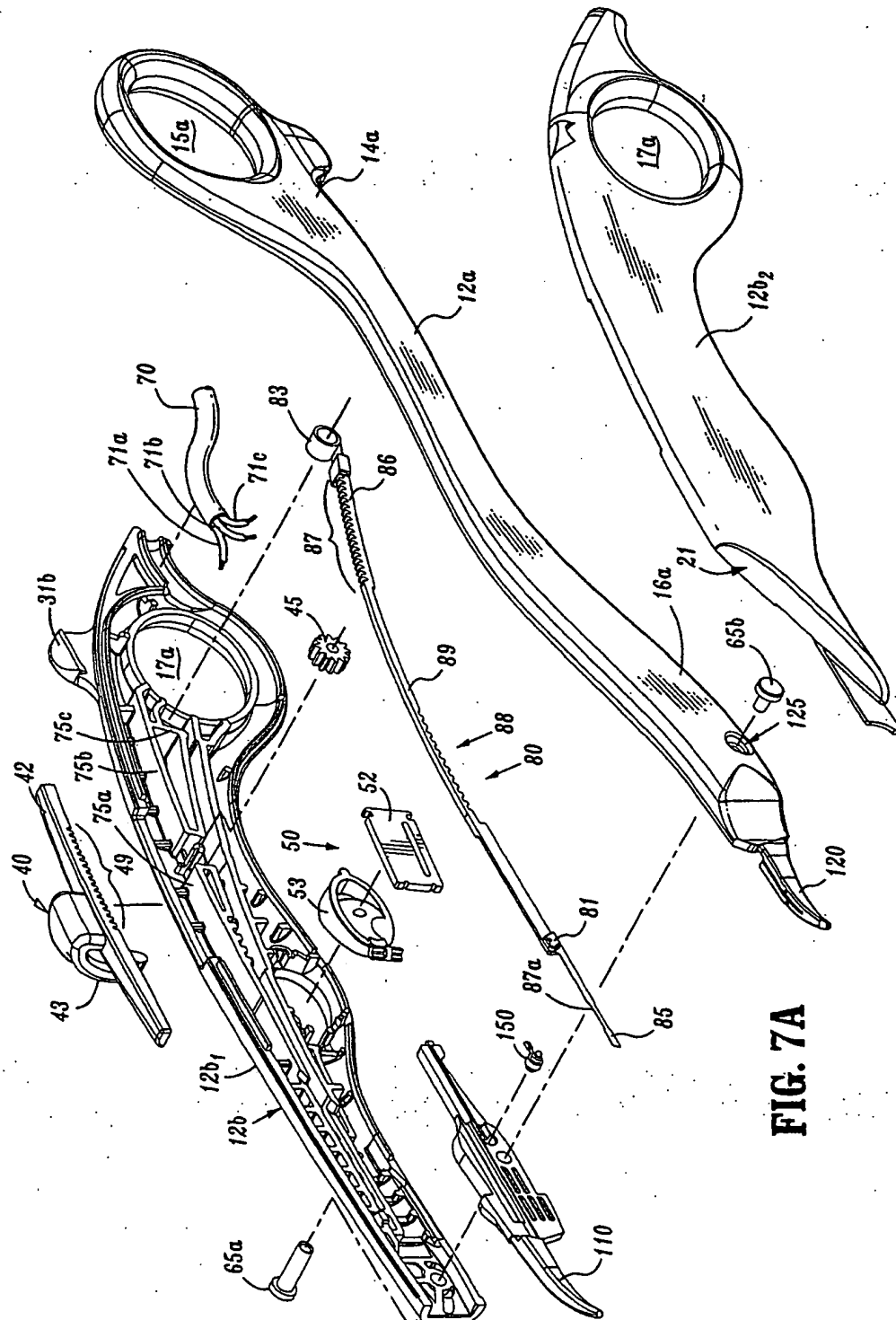


FIG. 7A

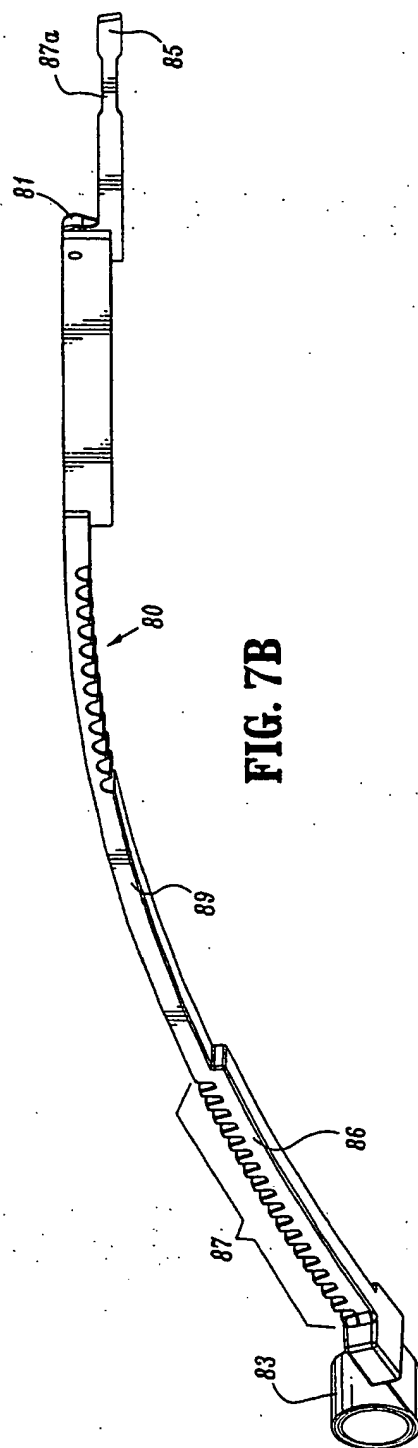


FIG. 7B

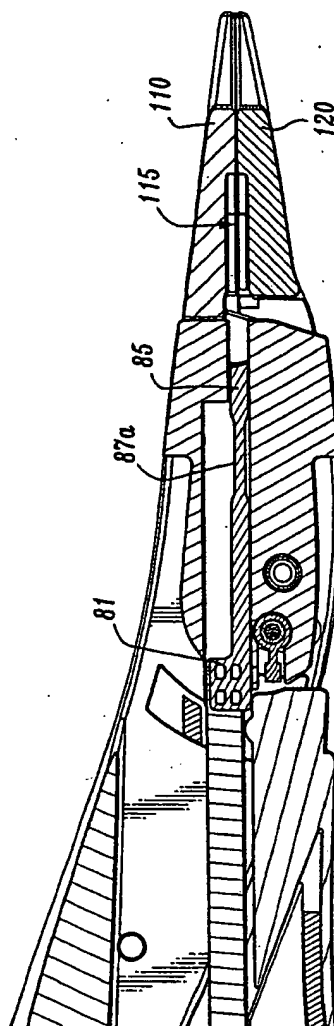


FIG. 7C

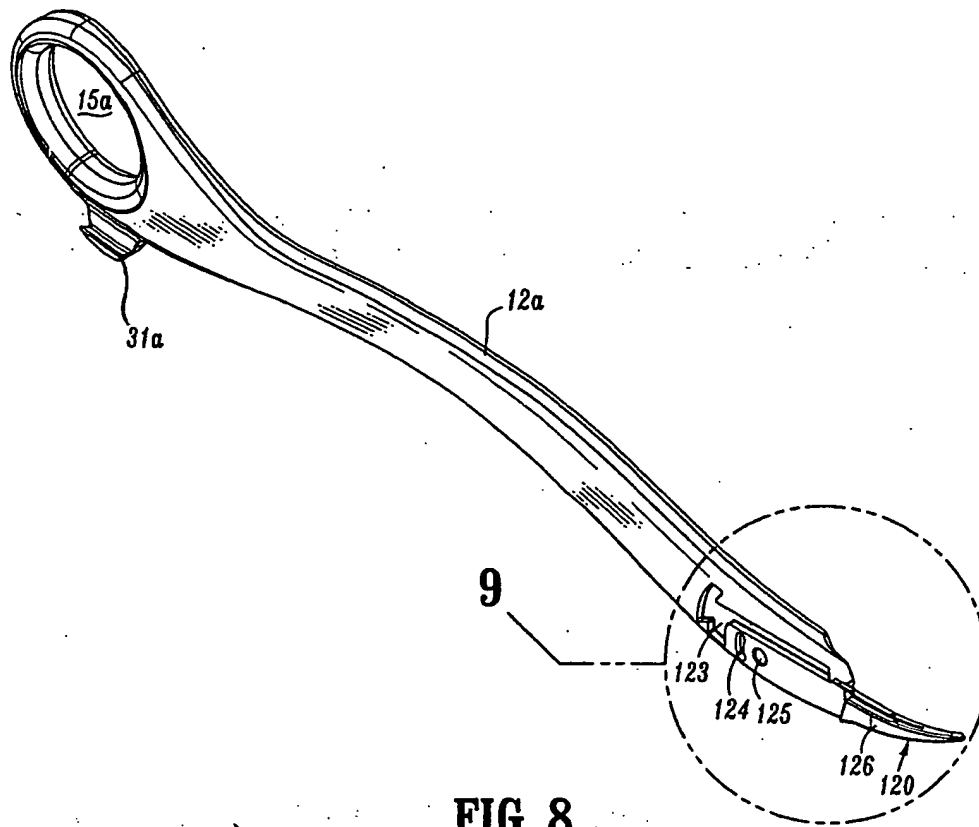


FIG. 8

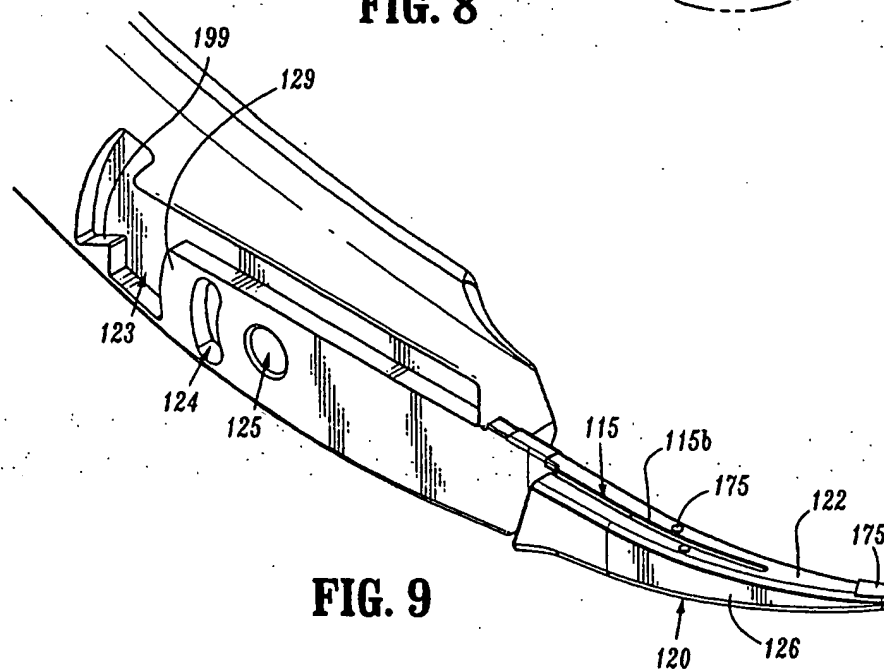


FIG. 9

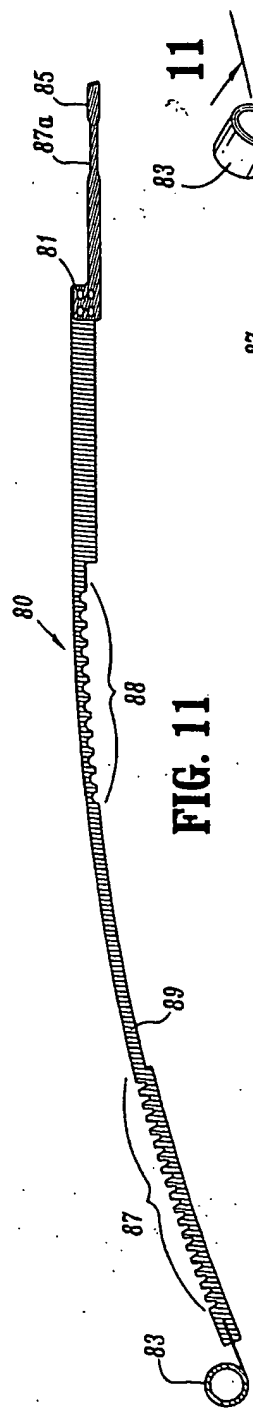


FIG. 11

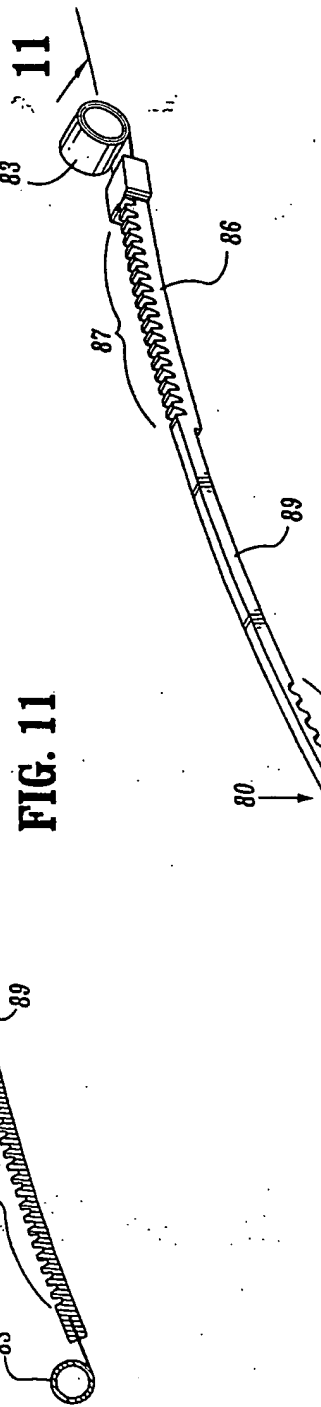


FIG. 10

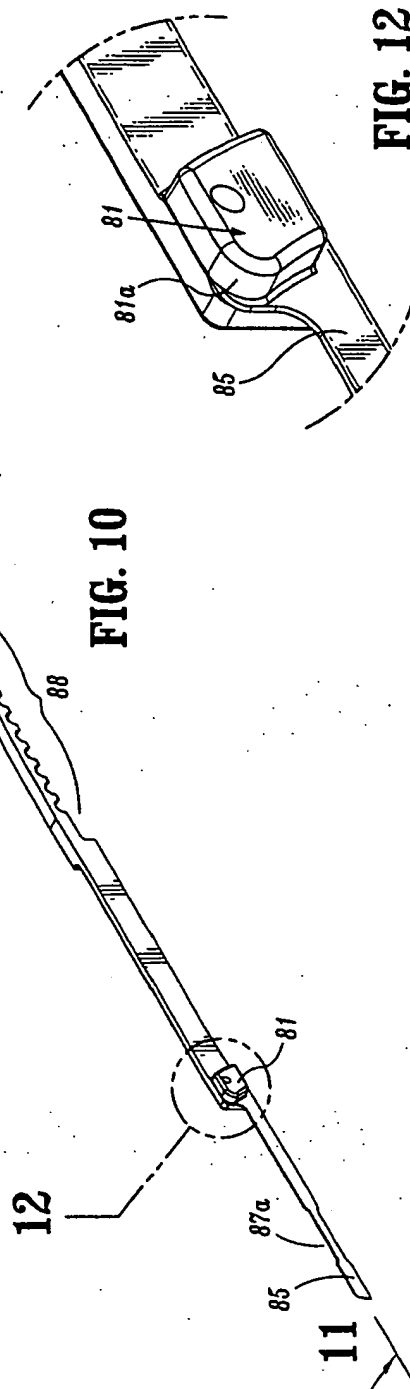


FIG. 12

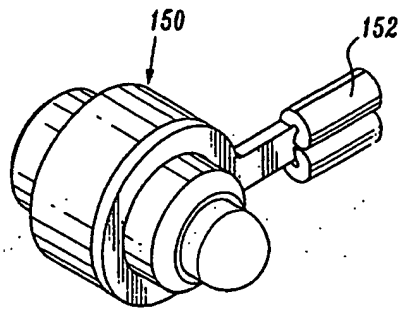


FIG. 13

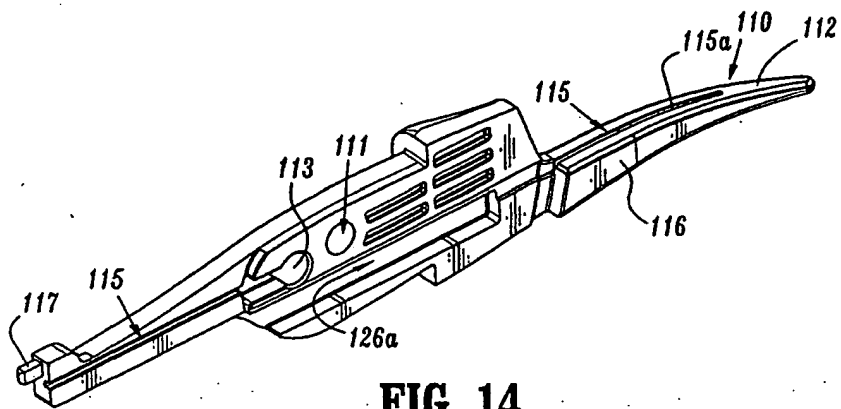


FIG. 14

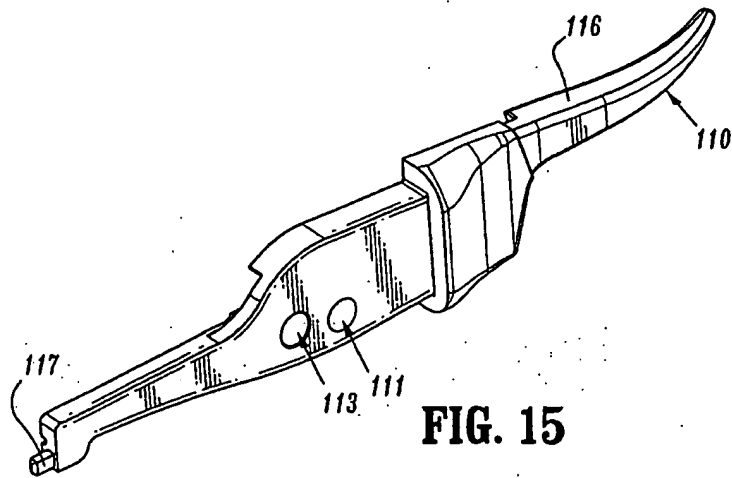
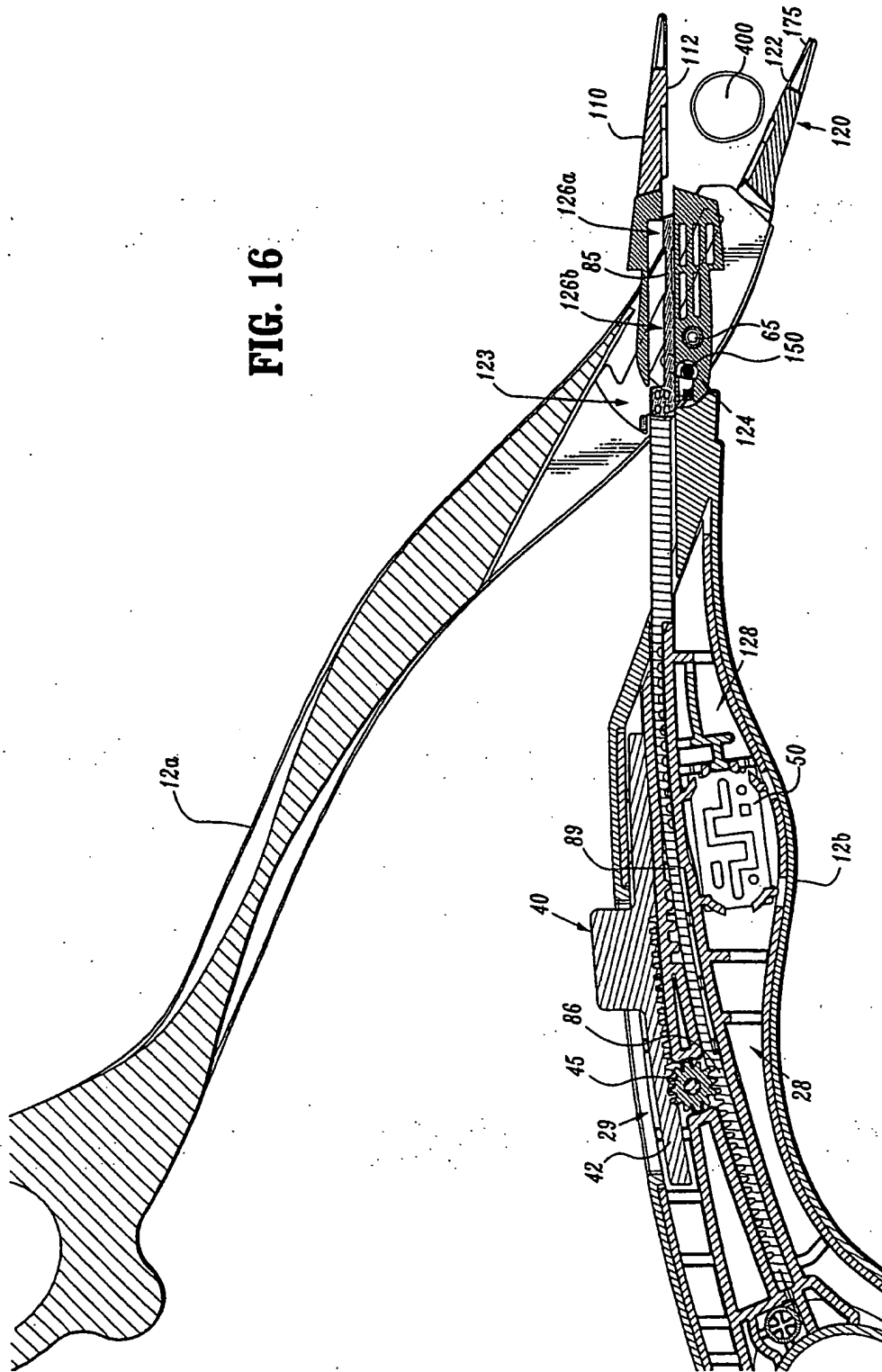


FIG. 15

FIG. 16



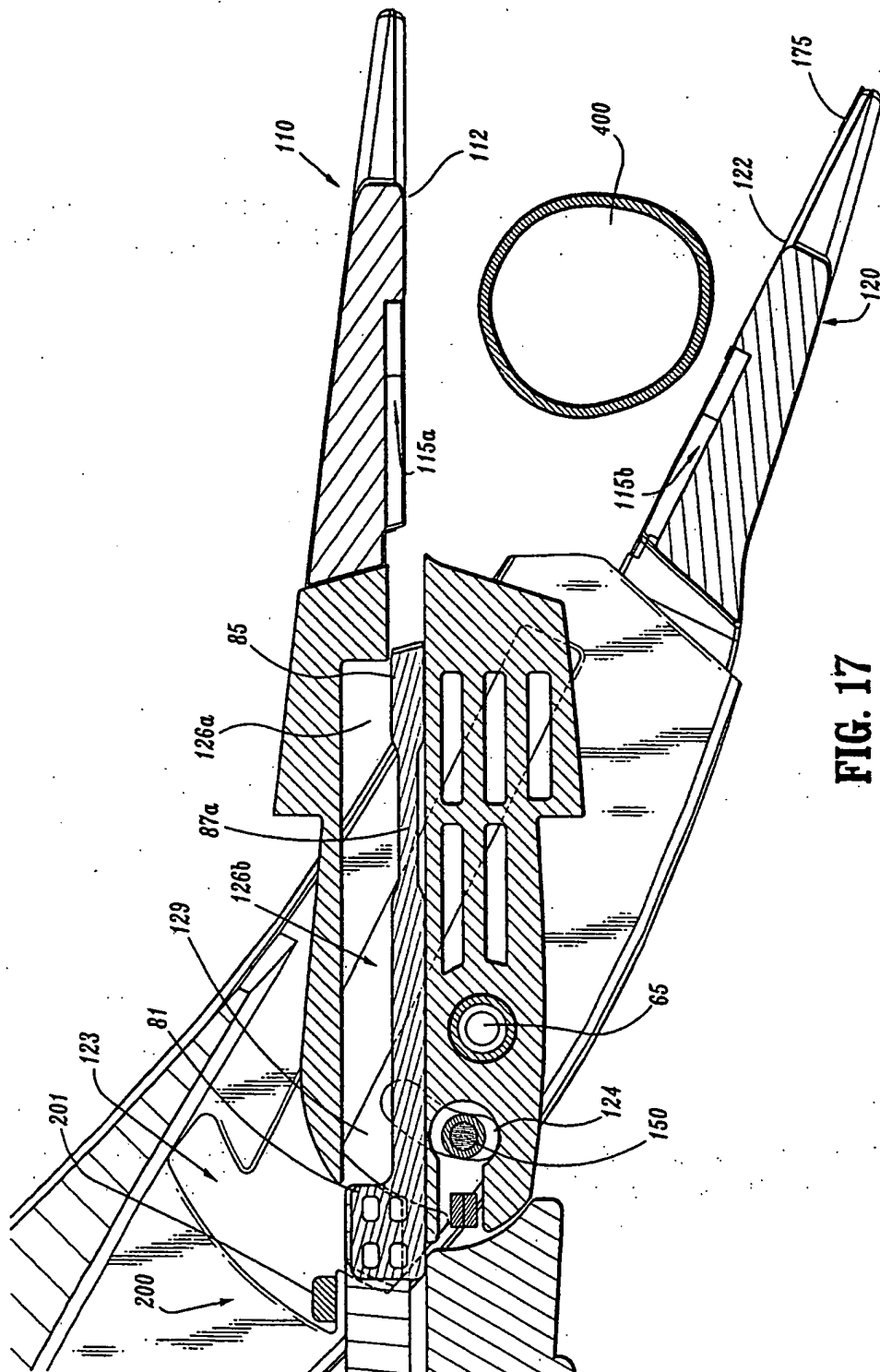


FIG. 17

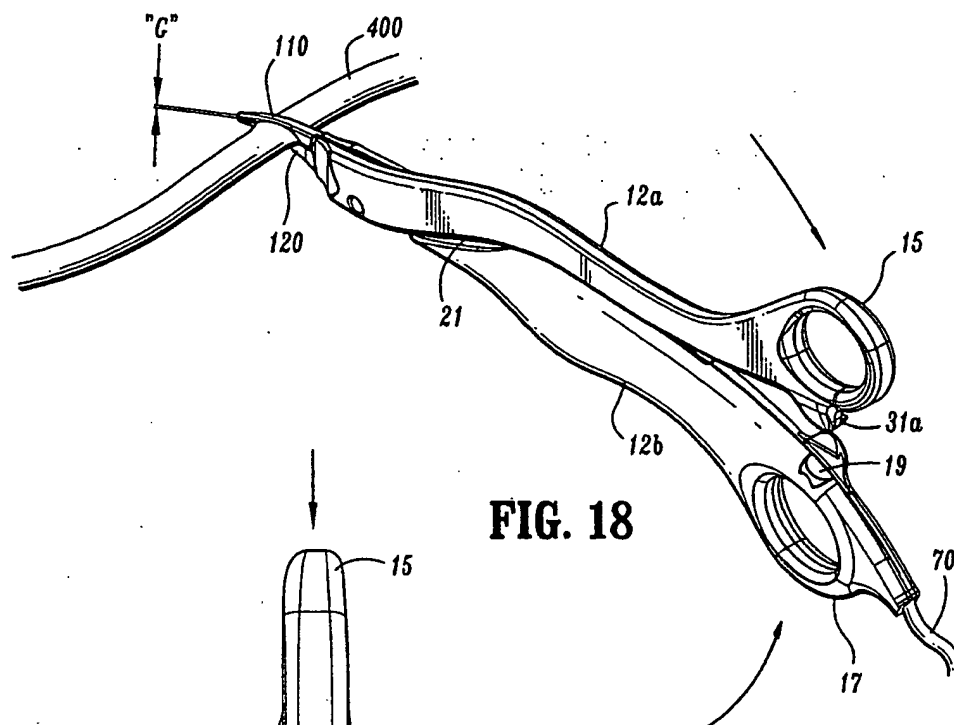


FIG. 18

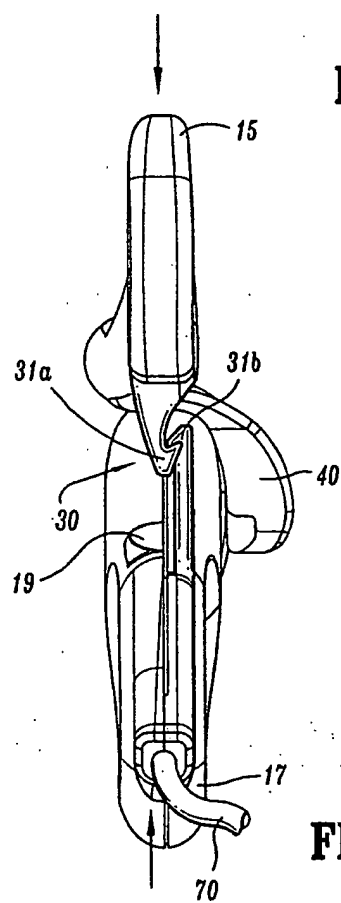


FIG. 19

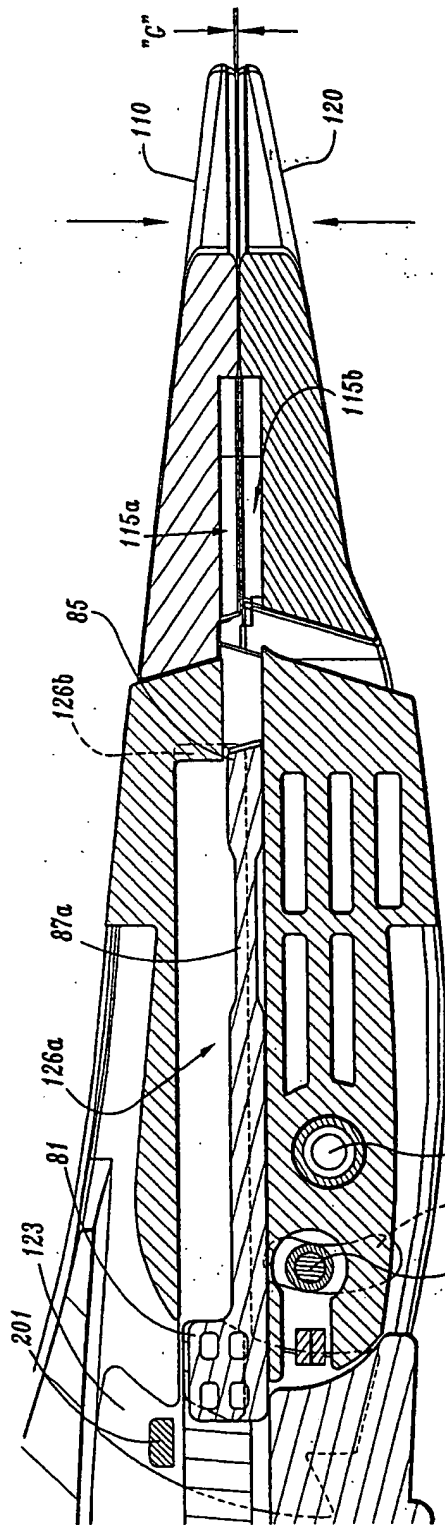


FIG. 20

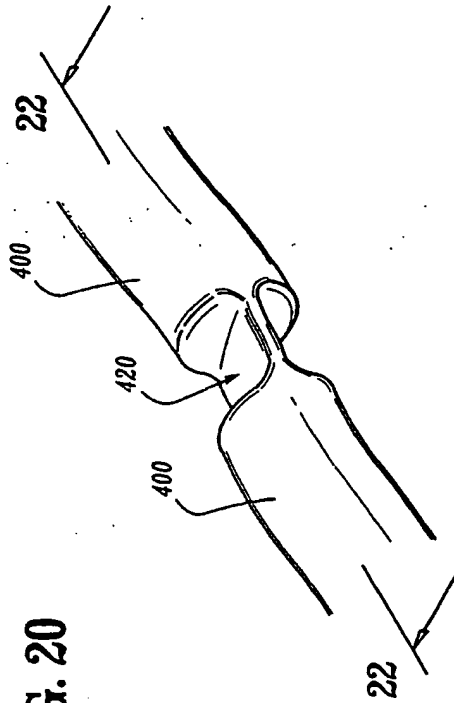


FIG. 21

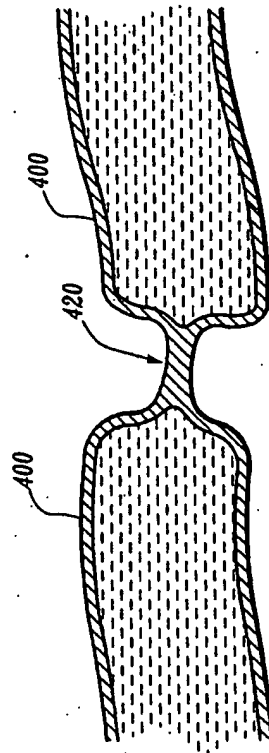


FIG. 22

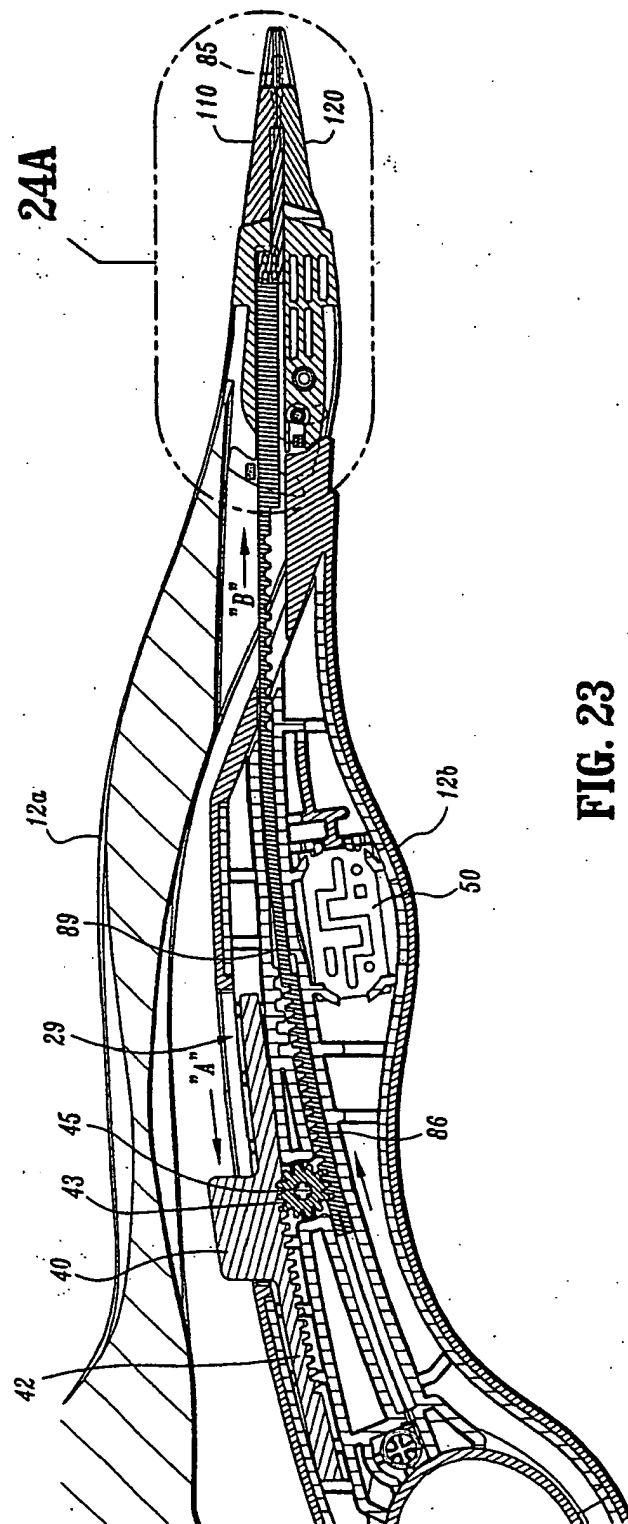


FIG. 23

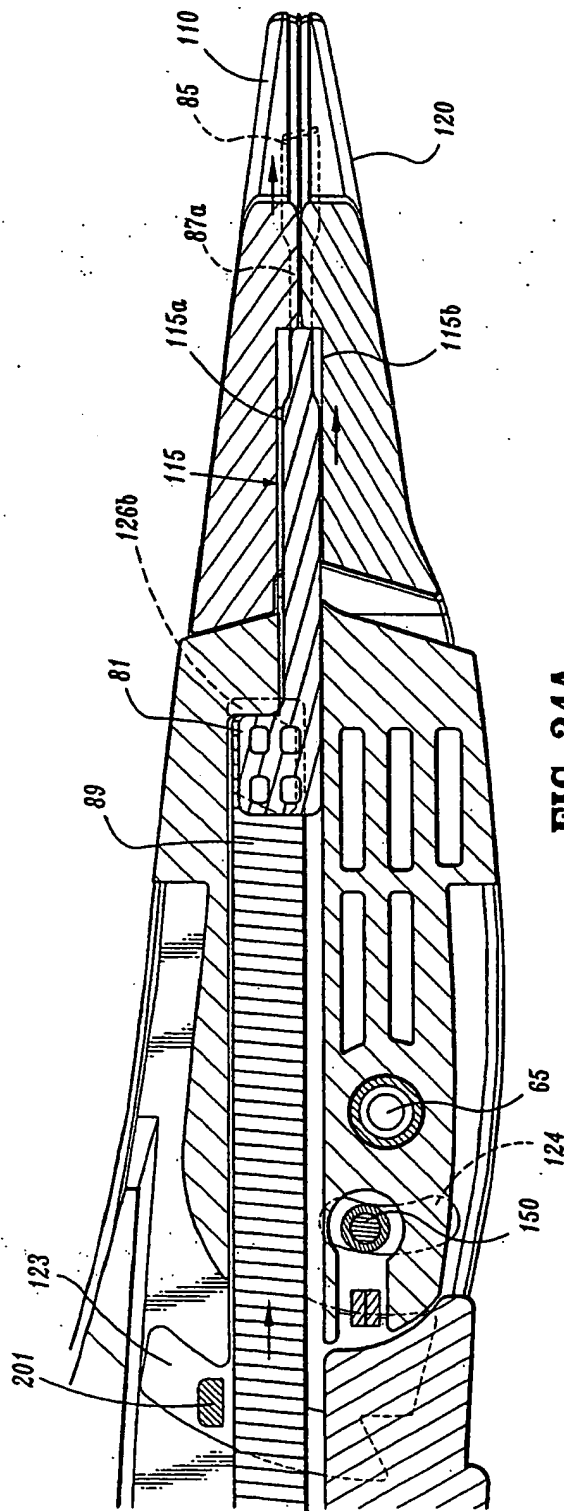


FIG. 24A

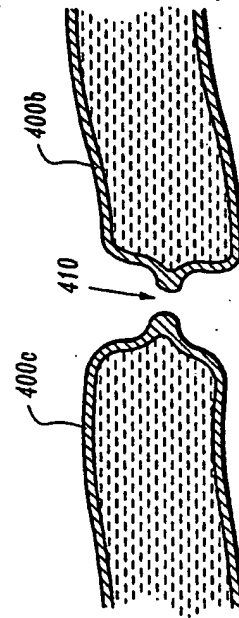


FIG. 25

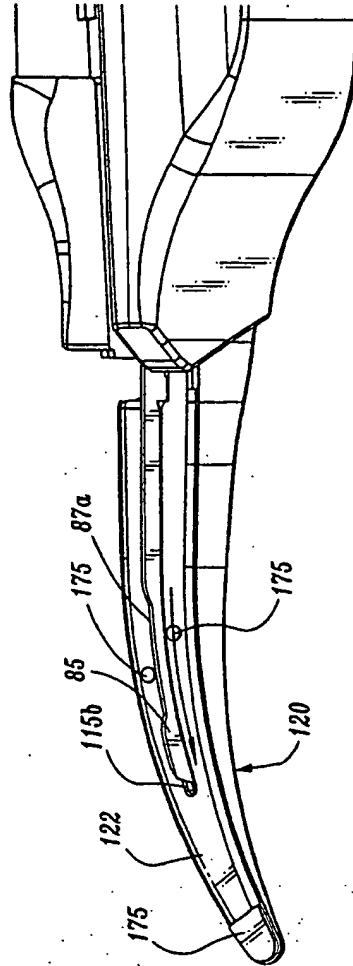


FIG. 24B



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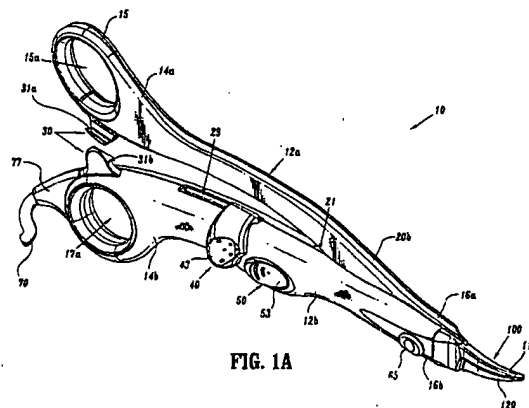
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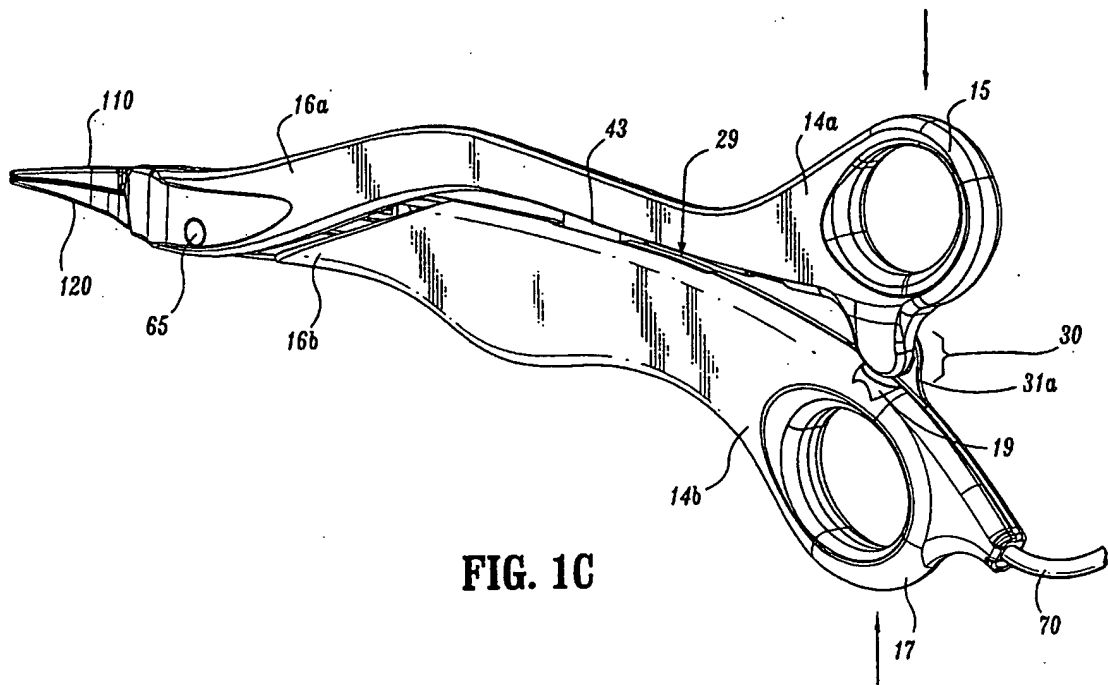
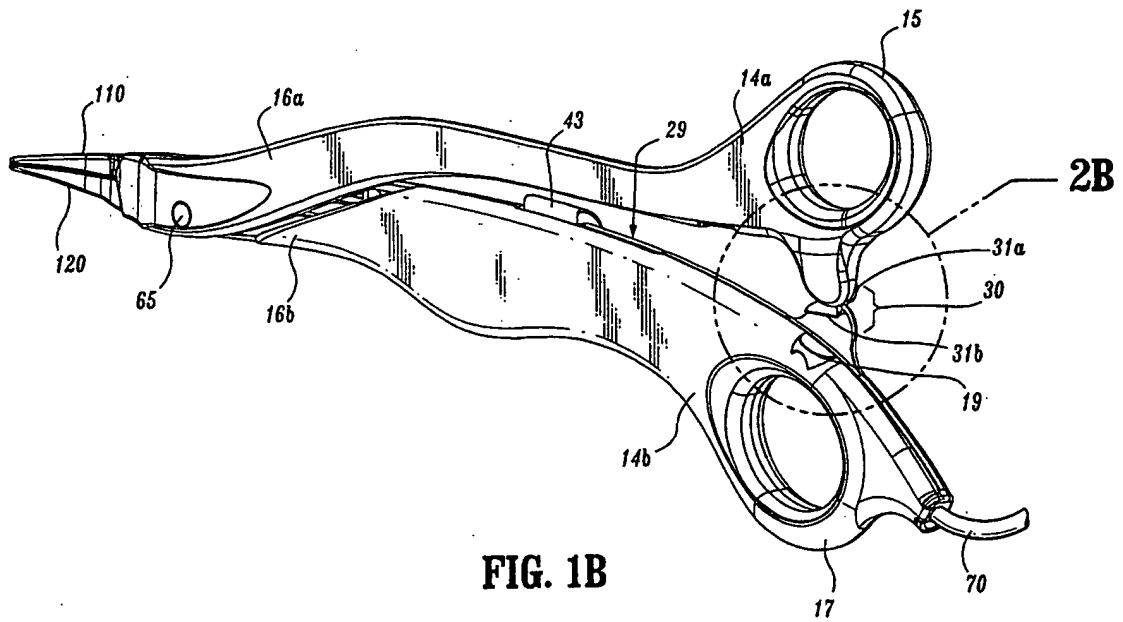
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(54) **Open vessel sealing instrument with hourglass cutting mechanism and over-ratchet safety**

(57) An open electrosurgical forceps for sealing tissue includes a pair of first and second shaft members each having a jaw member disposed at a distal end thereof. The jaw members are movable from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween. Each of the jaw members includes an electrically conductive sealing plate for communicating electrosurgical energy through tissue held therebetween. At least one of the jaw members includes a knife channel defined along a length thereof which is dimensioned to reciprocate a cutting blade therealong. An actuator is included which is operatively connected to one of the shaft members and selectively advances the cutting mechanism from a first position wherein the cutting blade is disposed proximal to tissue held between the jaw members to at least one subsequent position wherein the cutting blade is disposed distal to tissue held between the jaw members. The cutting blade is a generally hourglass-shaped flexible cutting blade having a notch disposed generally midway therealong which facilitates distal translation of the knife within the knife channel.







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EUROPEAN SEARCH REPORT

Application Number
EP 05 02 1937

DOCUMENTS CONSIDERED TO BE RELEVANT			
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The present search report has been drawn up for all claims			
Place of search Berlin		Date of completion of the search 6 March 2006	Examiner Abraham, V
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

4 EPO FORM 1503 03.02 (P04C01)



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EUROPEAN SEARCH REPORT

Application Number
EP 05 02 1937

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (IPC)
Place of search Berlin		Date of completion of the search 6 March 2006	Examiner Abraham, V
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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European Patent
Office

Application Number
EP 05 02 1937

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



European Patent
Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number

EP 05 02 1937

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-5

An open electrosurgical forceps comprising a generally hourglass-shaped flexible blade.

2. claims: 6,7

An open electrosurgical forceps comprising a ratchet configured to maintain a pressure between the jaw members within the range of 3 kg/cm² to 16 kg/cm².

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 05 02 1937

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

06-03-2006

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